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# Federal Policies and Prescription Drugs

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**Federal Policies and Prescription Drugs**

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University

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To my lovely wife:

Mandana

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# Chapter 1: Introduction

## Overview and Structure of the Dissertation

This dissertation comprises three discrete empirical papers, with an introductory essay that evaluates the impact of different federal policies on prescription drug prices, utilization, and spending. Two main databases are used: (a) Medicaid State Drug Utilization Data and (b) the Medical Expenditure Panel Survey (MEPS) data. These two databases are designed to track Medicaid drug utilization and overall medical use and expenditures, respectively. The variables of interest in this dissertation are prescription drug price, prescription drug use and spending, and overall drug expenditures.

The objective of the first paper (Chapter 2) is to examine whether oncology drug prices have significantly changed because the Medicaid rebate increased under the Patient Protection and Affordable Care Act (ACA). The analytic sample includes top-selling oncology drugs, both branded and generic, over an 8-year time period. The prices of top-selling oncology drugs in 2006 were followed through 2013 to find the extent to which drug prices have changed while controlling for state fixed-effect, package size, type of manufacturer, brand or generic, and drug strength. Thus, this study examines whether and to what extent oncology drug prices have changed after the increase in the Medicaid rebate under the ACA.

The second paper's objective (Chapter 3) is to study whether Medicare Part D has reduced racial disparities in diabetes drug use, coverage, and spending since its implementation in 2006. The analytic sample includes individuals aged 55 years and older who had diabetes from 2001 to 2010. Although the impact of Medicare Part D has been studied from different

perspectives, its impact on racial disparities in drug use, coverage, and expenditures among diabetics has not been studied yet.

The third paper (Chapter 4) focuses on the association between closing the Medicare doughnut hole and prescription drug utilization and spending for Medicare Part D beneficiaries with chronic diseases through 2013. The objective of the third paper is to determine whether the provisions of the ACA that close the coverage gap have affected prescription drug utilization and out-of-pocket (OOP) spending among Medicare seniors with Part D coverage.

The results of this dissertation can help policymakers to understand the extent to which Medicare beneficiaries with diabetes were affected by Part D and how the provisions of the ACA that close the coverage gap have affected prescription drug use and spending for Medicare Part D beneficiaries. It also can help to find whether increasing the Medicaid rebate was associated with increases in cancer drug prices.

## Significance of the Dissertation

This dissertation examines how closing the coverage gap and Medicare Part D have affected prescription drug utilization and spending for Medicare Part D beneficiaries. Also, it studies how oncology drug prices have changed after the increase in the Medicaid rebate under the ACA. Although there is some literature on how Medicare Part D has affected prescription drug utilization and OOP spending, there are several gaps that limit understanding. This dissertation addresses these limitations and contributes to the understanding of racial disparities in drug use and expenditures among diabetics, understanding of the impact of

closing the coverage gap on prescription drug utilization and spending, and understanding of oncology drug price changes after the ACA Medicaid rebate increase.

Although prior research has primarily analyzed the impact of the initial Medicaid rebate without controlling for specific characteristics of manufacturers or drugs, no study has analyzed how oncology drug prices changed after the ACA Medicaid rebate increase. In other words, previous literature has only examined the Medicaid rebate of 1991. This study is among the first to estimate changes in oncology drug prices after the current Medicaid rebate increase while controlling for type of manufacturer (brand or generic), package size, drug strength, coverage type, and state and year fixed effects.

Second, despite existing racial disparities in drug use and expenditures prior to Medicare Part D, only one study has examined the aggregated effect of Part D on racial disparities in drug use and expenditures. This study is among the first to specifically examine whether and to what extent Medicare Part D has affected racial disparities in drug use and expenditures among beneficiaries with diabetes.

Third, prior literature has mostly focused on the impact of Part D on drug utilization and spending. This study is significant in that it is among the first to measure whether the provisions of the ACA that close the coverage gap have affected prescription drug spending and utilization among Medicare seniors with Part D coverage. This can help policymakers understand the financial impact of cost sharing and drug discount on utilization and spending among Medicare beneficiaries.

## Chapter 2: The ACA Medicaid Rebate and Medicaid Drug Prices for Cancer

### Summary

Prescription drug spending is a significant component of Medicaid total expenditures.[1] Numerous policies have aimed at controlling Medicaid prescription drug spending;[2] however, these policies could have unintended impacts on drug prices and utilization.[2–7] Among these policies is the Medicaid rebate that, under the Omnibus Budget Reconciliation Act of 1990, allows Medicaid to pay drug manufacturers the lowest price offered to any buyer. Under the Affordable Care Act (ACA), beginning in 2010, the Medicaid rebate for branded drugs increased from 15.1 to 23.1 percent of the average manufacturer price.[8] It is unknown to what extent pharmaceutical companies will respond to this increase and how the rebate may change drug prices paid by Medicaid, particularly oncology drugs, across states.[9–12] However, one approach to offset the rise is to increase drug prices for chronic conditions such as cancer, which is well represented across payers.[13]

Cancer is the second cause of death after heart disease,[14] and it accounts for about one-fourth of Medicaid spending on specialty drugs.[15] In this paper, I examine the extent to which oncology drug prices changed after the increase in the Medicaid rebate in 2010, using Medicaid state drug utilization data from 2006 to 2013.[16] The Medicaid State Drug Utilization Data allow tracking of Medicaid drug utilization and spending by national drug code in all 50 states, yearly and quarterly. It also allows the calculation of average reimbursed price, because the dataset provides information about package size, units reimbursed, and amount reimbursed by Medicaid and non-Medicaid insurers. I will focus on top-selling oncology drugs by either unit

sold or retail sales in 2006. This includes top-selling drugs for breast, ovarian, bladder, prostate, colorectal, and lung cancer, and leukemia, because they have the highest incidence and mortality rates compared to other types of cancer.[17]

## Introduction

Medicaid was created under the Social Security Act of 1965 to help states provide health care coverage for low-income children and families, disabled people, poor seniors (individuals ≥65 years), and pregnant women. Medicaid is the largest health coverage program in the United States and covers more than 60 million people.[18,19] Although Medicaid is jointly funded by the federal and state governments, states have the authority to determine coverage criteria, the scope of services offered, and the process for reimbursing health care providers.[20] Outpatient prescription drug coverage is an optional service that states provide with relatively low cost sharing due to federally mandated low copayments and deductibles. However, it is one of the main challenges for states, as Medicaid covers low-income populations with high health care needs, prescription drug spending comprises a significant part of Medicaid total expenditures, and Medicaid has limited ability to negotiate with drug manufacturers over prescription drug prices.[1, 21–32]

To secure better prices, control Medicaid drug spending, and eliminate price discrimination generated by Medicaid's limited negotiating power, the Medicaid rebate program was created by the Omnibus Budget Reconciliation Act of October 1990 (OBRA 90). Under OBRA 90, drug manufacturers who sign a rebate agreement with the Secretary of Health and Human Services receive access to the Medicaid market in exchange for payment of a rebate.[33,34] Under the Medicaid Drug Rebate Program, pharmaceutical manufacturers must pay a quarterly rebate directly to state Medicaid programs; the rebate is calculated based on average manufacturer price (AMP) and best price.[33,34] AMP is the average price paid by

wholesalers to pharmaceutical manufacturers for drugs that are distributed to retail pharmacies; best price is the lowest price charged to any U.S purchaser. The goal of the best price is to secure the lowest possible price for Medicaid compared to other purchasers who are allowed to use bargaining power. Because manufacturers must release their best prices to the Centers for Medicare and Medicaid Services (CMS), they are discouraged from giving steep discounts to other buyers. The rebate for all innovator single- or multiple-source branded drugs (those with a valid patent) was established by OBRA 90 as equal to 15.1 percent of the AMP or the difference between the AMP and the best price, whichever was greater. On the other hand, rebate amounts for non-innovator (generic) drugs were 11 percent of AMP.[33]

Medicaid rebates and their association with drug prices are especially important for Medicaid beneficiaries with cancer. First, cancer is the second leading cause of death after heart disease in the United States.[35] There are more than 580,000 cancer deaths each year in the U.S.; breast, lung, pancreatic, colon, and colorectal cancers constitute most cancer deaths.[35] Second, oncology products that are in research and development pipelines comprise more than one-third of all research drugs, and they are estimated to increase specialty drug spending.[36] About 150 drugs are currently under research and development to treat cancer, which is estimated to significantly increase national drug spending.[37,38] Third, the share of total U.S. medical expenditures for cancer grew more rapidly for Medicaid than other payers.[39] In other words, the share of cancer treatment costs paid by Medicaid tripled, to more than $7 billion; and increases in the prevalence of cancer account for 86 percent of overall cancer costs.[39,40] Fourth, the cancer prevalence rate is higher among Medicaid recipients compared to the national prevalence rate and the uninsured population.[41] Cancer prevalence was 1.2 to 5.2

times higher among the Medicaid population compared to the national level.[41] Fifth, Medicaid beneficiaries are in significantly worse health than adults who receive their coverage from an employer or insurance other than Medicaid.[42] Finally, about 50 percent of oncology practices' income comes through the "spread," which is the difference between what pharmacies or prescribers actually pay for a drug and the average wholesale price (AWP), which is used for reimbursement by insurance companies.[43]

Under the ACA, there were changes to the Medicaid rebate for the purpose of reducing Medicaid prescription drug spending. First, starting in 2010, the Medicaid rebate increased from 15.1 to 23.1 percent of the AMP for innovator drugs—that is, branded drugs with a valid patent. In other words, 23.1 percent of the AMP or the difference between the AMP and the best price per unit, whichever is greater, was applied to assess rebates. Also, the rebate amount for generic drugs increased from 11 percent to 13 percent of the AMP per unit.[8] This means that Medicaid collects more rebates compared to the years prior to the ACA and overall Medicaid spending on prescription drugs is reduced. In other words, pharmaceutical firms now have to pay back a higher amount of money to state Medicaid agencies. Additionally, not only outpatient prescription drugs that are covered under Medicaid fee-for-service (FFS) but also outpatient prescription drugs that are covered under Medicaid managed care organizations (MCO) are used to assess the Medicaid rebate.[33,34] Coverage type is important, because individuals who have FFS coverage face no cost sharing or low copayments for filling prescription drugs. However, individuals with MCO coverage are more responsive, because they face cost sharing or copayments for filling prescription drugs. In addition, MCOs have some degree of negotiating power compared to FFS.

The increases in the ACA Medicaid rebates were implemented in March 2010; however, due to a lag in reporting and calculating, the increases in rebates became effective as of January 2010. In other words, it was retroactive due to the nature of rebate calculation. Rebate amounts are paid on a quarterly basis; to calculate the rebate amounts, manufacturers must report the best price and AMP for each drug to the CMS within 30 days of the end of each calendar quarter. In addition, states need to report the Medicaid utilization for each covered drug in the quarter to the manufacturer within 60 days of the end of the quarter. Then, the manufacturer computes and pays the rebate amount to each state within 30 days of receiving the utilization information. Although it has been claimed that the Medicaid rebate helped states to reduce their spending,[44] it is unknown to what extent oncology drug prices change after the Medicaid rebate, as oncology drugs comprise the biggest share of prescription drug spending. Thus, this study can help policymakers to understand how oncology drug prices have changed after the ACA. Also, it shows the extent to which oncology drug prices varied by coverage type (FFS vs. MCO).

**Literature Review**

This section discusses prior research on the correlation between the Medicaid rebates and prescription drugs. This includes a review of literature on the effect of Medicaid drug procurement, generic competition, and assessed fees on drug prices paid by Medicaid, utilization, and spending. First, I review the recent literature relevant to the correlation between the Medicaid rebates and drug prices, followed by a review of the literature on the effects of the Medicaid rebate on overall Medicaid prescription spending. This is followed by

the literature on the effect of the Medicaid rebate on drug access and market concentration. Finally, I review the recent literature trends in cancer drug prices. This section concludes with a summary of findings and demonstrates information gaps to highlight the necessity for further research regarding Medicaid rebate effects on drug prices paid by Medicaid.

**Drug Prices**

Several studies have been conducted since the inception of the Medicaid rebate program to examine the association between the Medicaid rebate and drug prices. In studies that have looked only at the association between the Medicaid rebate and drug prices, the magnitude of the effect depended on the type of drug, drug market share, and the difference between AMPs and the best price.[45-47] The findings show that after the Medicaid rebate program began, pharmaceutical manufacturers reduced the amount of their best price discounts to private buyers, raised the AMPs, and charged higher launch prices.[45-48] The seminal research that examined the effect of the Medicaid rebate was conducted by Fiona Scott Morton.[46] She used a cardiovascular subset of IMS Health's Drugstore and Hospital Audit data from 1989 through 1991 to investigate the extent to which pharmaceutical companies responded to the introduction of the Medicaid rebate in 1990. Using an ordinary least squares regression, she found the AWP of competitive cardiovascular brand drugs—those facing generic competition—rose about 4 percent, while the price of cardiovascular branded drugs did not significantly increase. She also found that generic manufacturers raised their drug prices once their markets become more concentrated. Morton concluded that the Medicaid rebate program increased drug prices for non-Medicaid consumers.[46]

None of the existing studies quantified and examined the association between the Medicaid rebates and drug prices by therapeutic class and manufacture type or by coverage type. These are important, as drug prices could vary by therapeutic class* and manufacturer type (generic vs. brand). Thus, the results of these articles are not generalizable to branded drugs in therapeutic classes other than cardiovascular. In addition, these studies did not include generic drugs in their sample of drugs studied.

**Medicaid Spending**

Existing literature demonstrates that the Medicaid rebate reduced Medicaid's overall prescription spending. Using the CMS data on drugs dispensed in retail pharmacies in 2009, the Office of the Inspector General for the U.S. Department of Health and Human Services found that Medicaid was paying almost one-quarter of what Medicare paid for 100 high-spending branded and generic drugs. The study concluded that the Medicaid rebate program significantly reduced Medicaid program costs.[44] They also found that unadjusted wholesale acquisition costs (WAC), AMPs, and Medicaid payment amounts increased by 27, 34, and 40 percent, respectively. However, the Medicaid rebate program had generated enough savings to offset increases in branded drug prices.[49] This shows that Medicaid's net costs for branded drugs increased at a lower rate than inflation. Additionally, a study conducted by the U.S. Government Accountability Office showed that Medicaid paid the lowest average net prices

*Specialty drugs like medications for cancer and hepatitis C are more expensive than nonspecialty drugs like medications for hypertension and hyperlipidemia.

across a sample of about 80 high-utilization and high-spending branded and generic drugs, compared to Medicare and the Department of Defense.[50]

A general limitation of existing literature is the lack of a representative sample. The studies have focused only on the top 100 high-spending or high-utilization drugs instead of quantifying the effect by therapeutic class.[49] Although the sample size included the top 100 high-spending or high-utilization drugs, the effect may be varied or less significant for acute conditions and special cases such as cancer. Also, they did not control for other potential factors, such as substitution effects and package size, which could result in biased estimates. Drugs with a larger package size are usually cheaper than drugs with smaller package size, and the availability of a substitute can affect both drug price and utilization.[51,52] Taking substitution effects and package size into account would enhance the validity of estimates.

**Access and Market Concentration**

Prior research has shown that the Medicaid rebate increased access to medications and that Medicaid market share is positively correlated with drug prices. In studies that have looked at the association between the Medicaid rebate and drug access, Okunade found that the Medicaid rebate program increased access to prescription drugs by stimulating retail transactions.[53] Research has also shown that lower pre-rebate reimbursement rates increased the market concentration of generic drugs; higher Medicaid market share was associated with higher average drug prices.[54,55] Duggan found that a 10 percentage point increase in the Medicaid market share was associated with a 7 to 10 percent increase in the average price of the 200 top-selling drugs using IMS health data and the CMS drug utilization files from 1997 to

2002.[56] The average price of the 200 top-selling drugs paid by non-Medicaid payers would have been 13 percent lower if Medicaid pricing policies had not been in place. These studies showed that the Medicaid rebate program may increase access to prescription drugs, but it may also increase the average price paid by non-Medicaid payers. However, none of the existing literature employed a sample of cancer drugs. The changes in drug prices could vary by therapeutic class because drugs for specific conditions might be overrepresented in the 200 top-selling drugs sample while other conditions had less representative drugs.

**Cancer Drug Prices**

Several studies have examined cancer drug prices and changes in price over time. Using the MEPS data, Tangka found that the medical costs of cancer have nearly doubled and the share of these costs paid for by Medicaid has increased.[39] Existing literature that examines trends in the launch prices for oncology drugs approved between 1995 and 2013 in the U.S. shows that the average launch price of anticancer drugs, adjusted for inflation and health benefits, increased by 12 percent annually—or an average of $8,500 per year.[48] Literature also shows that insurance payments per patient per month in the first year of chemotherapy for oncology drugs more than doubled in 10 years; growth in drug prices both at launch and post-launch contributed to payer spending growth.[57] In addition, following the loss of U.S. patent exclusivity for oncology drugs, average monthly price declined by more than 20 percent after generic entry. However, average prices for drugs produced by branded manufacturers rose, while prices for drugs produced by generic manufacturers fell upon patent expiration.[58]

**Literature Gap**

The recent increase in the Medicaid rebate through the ACA and the application of Medicaid rebates to drugs that are covered through managed care plans has not yet been studied, especially for oncology drugs. Existing literature examines the association between the Medicaid rebates and drug prices, access to medication, and Medicaid program cost. Overall, the literature demonstrates that the Medicaid rebate policy has been beneficial for the Medicaid program and has reduced costs through generating enough savings to offset increases in drug prices. Prior research suggests that the Medicaid rebate encourages manufacturers to increase drugs' AMPs and to reduce the size of discounts to private payers. However, the existing literature does not stratify the effect of Medicaid rebate by therapeutic class, coverage type, or manufacturer type (brand or generic). These factors are important, as specialty drugs, such as medications for cancer, are more expensive than non-specialty drugs, and coverage type could affect drug prices. This study contributes to the literature because it is the only one that estimates the association between the increase in the Medicaid rebates under the ACA and changes in oncology drug prices. Since 1997, no study has been conducted to measure the association between the Medicaid rebate and drug prices. Conducting this study will show the extent to which oncology drug prices have changed after the increase in the ACA Medicaid rebate while controlling for prescription drug coverage type, package size, and type of manufacturer.

**Aims and Hypotheses**

Prescription drug prices play an important role in increasing healthcare costs, especially for Medicaid due to its limited negotiating power. Although the Medicaid rebate aims to secure better prices and reduce Medicaid drug spending, it could have unintended effects on drug prices by encouraging pharmaceutical firms to increase drug prices, particularly for specialty drugs such as cancer drugs that have a high profit margin.

I propose to examine the extent to which oncology drug prices changed after the recent increases in the ACA Medicaid rebate. The basic intuition is that pharmaceutical firms now have to pay back a higher amount of money to state Medicaid agencies. In addition, drug prices paid by Medicaid are a set fraction of the average price paid by non-Medicaid payers. Therefore, manufacturers could increase drug prices to offset the higher costs. The effect would be higher for brand-name drugs, as they face a higher rebate increase compared to generic drugs and are also more expensive than generics. An increase in rebate would have a bigger impact on the rebate amount, especially for brand-name drugs. The study will determine whether oncology drug prices have changed since the Medicaid rebate increased in 2010. The specific aim is:

1. Examine changes in oncology drug prices after the ACA Medicaid rebate increases.

H1: Medicaid prices for oncology drugs will increase following the Medicaid rebate because firms may offset the cost of higher rebates that they have to pay to the Medicaid.

H2: Drug price indicators such as WAC will increase for brand-name drugs following the Medicaid rebate increase because existing drug prices in the private market are used to set the Medicaid prices.

H3: Oncology drug prices will be lower for drugs that are covered under Medicaid managed care compared to FFS plans.

**Conceptual Framework and Economic Theory**

Price discrimination occurs when a pharmaceutical company charges different prices to different consumers for an identical drug. The economic theory behind this behavior is based on price elasticity of demand. Consumers who have inelastic demand are more likely to be charged a higher price compared to consumers with elastic demand. Low-income consumers have higher price elasticity, meaning their consumption will decrease if drug prices increase.

As Medicaid recipients who are not enrolled in a managed care plan face no cost sharing or low copayments for filling prescription drugs, once they enroll in the program they have perfectly inelastic demand for prescription drugs.[56] Although Medicaid has some leverage—such as a preferred drugs list, prior authorization, and supplemental rebates—to control large increases in drug prices, inelastic demand for Medicaid recipients may create significant incentives for pharmaceutical firms to raise drug prices in the private market, especially when they face financial burdens such as rebates. In addition, as the government relies on existing prices in private sectors, tying drug prices paid by Medicaid to the AMP and the best price can adversely affect other consumers who have private insurance or are uninsured via increasing drug prices.

For a pharmaceutical firm that has a patented drug, the drug has a constant marginal cost and the demand for the drug does not influence the demand for other products produced by the same firm. Thus, the company has market power due to patent protection. Based on a model proposed by Duggan,[59] the drug price is associated with demand elasticity at the optimal price. Therefore, the greater the inelasticity in demand, the higher the price. However, in the Medicaid market, the optimal price is associated with the ratio of Medicaid prescriptions to non-Medicaid purchases and the reimbursement rate. In other words, as the number of Medicaid beneficiaries increases under the ACA, the effective demand elasticity declines, therefore prompting firms to pursue profit-maximizing behavior by increasing drug prices. Given the inelastic demand of Medicaid recipients, firms' market power over patented drugs, and Medicaid drug procurement that uses AMP and best price to set the Medicaid rebate, pharmaceutical firms can increase drug prices to non-Medicaid consumers in order to charge higher drug prices to Medicaid. Therefore, it is more likely to see manufacturers to increase drug prices in order to offset associated costs and maximize their profit.

Additionally, drugs sold in large package sizes or drugs with lower strength have a lower per unit price than those sold in small packages or have higher strength, respectively. As the government uses the best price to assess the rebate, drugs with a large package size are more likely to have the best price. Thus, firms are more likely to raise the price of drugs that have larger package sizes or lower strength compared to those with smaller packages or higher strength, respectively. In this analysis, I include drug characteristics as prescription drug prices are associated with drug package size, strength, and dosage form. I also include the type of service that Medicaid beneficiaries were covered under (FFS vs. MCO), as coverage types are

associated with drug prices. People with FFS coverage would show a different price elasticity than people with MCO coverage. In addition, MCOs have some degree of negotiation power compared to FFSs.

Overall, prescription drug prices are different by manufacturer type (brand vs. generic). In addition, coverage type and drug characteristics, including strength, package size and dosage form, can change drug prices. Therefore, this analysis controls for all these factors.

## Methods

### Data

This analysis uses 2006–2013 State Drug Utilization Data, collected by the Medicaid Drug Programs Data and Resources and maintained by the CMS. This publicly available database covers Medicaid beneficiaries in all states (except Arizona from 2006 to 2009).[60] The State Drug Utilization Data includes all outpatient drugs that have been paid for by state Medicaid agencies since the inception of the Medicaid rebate program. Each record in the database contains an 11-digit national drug code (NDC), state name, drug name, year and quarter of Medicaid spending, the total number of units of the drug reimbursed by the state, the number of prescriptions reimbursed, number of pharmacy claims, and Medicaid and non-Medicaid amount reimbursed (pre-rebate) to pharmacies, including drug costs and dispensing fees. Consistent with the literature, Medicaid amount reimbursed per unit was used as a proxy for generic drug prices covered by Medicaid, as the actual amount of rebates is not available to the public.[61-63]

To measure changes in brand-name drug prices for oncology, I used WAC, which is the list price for a pharmaceutical sold by a manufacturer to a wholesaler; WAC is consistent across the states for a given year, because it is a good representation of brand-name drug prices at retail pharmacies.[64] However, WACs do not perfectly reflect retail prices for generic drugs, as many generic manufacturers do not have a WAC and there is no legal requirement for them to report WACs.[65-68] Using WAC enabled me to have a generalizable estimate of how brand-name drug prices for cancer changed after the Medicaid rebates. I also chose WAC over AWP because experts believe that many AWPs are artificially inflated.[9,54] Therefore, it could result in overpayment of the ingredient costs for drugs by state Medicaid programs. To obtain WACs, I used First Databank.[†] First Databank is the market leader in publishing pharmaceutical drug prices that are used within healthcare systems serving hospitals, payers, retail pharmacies, and state health programs such as Medicaid. It is crucial for manufacturers to report their prices to First Databank because almost all payers use their prices to reimburse providers. Using this database allowed me to have more price indicators and control for all possible drug price changes through the year.

Finally, to obtain all drug-specific characteristics, including package size, dosage form, drug strength, manufacturer type (brand vs. generic), active ingredient, route of administration,

[†] http://www.fdbhealth.com/fdb-medknowledge-drug-pricing/

manufacturer, and re-packager,[‡] I used the Red Book[§], which is available through Micromedex at the University of Maryland in Baltimore.

**Analytic Strategy**

A pre-post study design was used to evaluate the correlation between the Medicaid rebate increase and oncology drug prices after 2010 while controlling for the trend in drug prices before the ACA was implemented. In this analysis, I focused on 25 top-selling brand-name and 10 top-selling generic drugs for cancer in 2006 and followed them through 2013. I chose these top-selling drugs because they constituted more than 90 percent of oncology drugs in either unit sold or retail sales in 2006. Over the time period of the analysis, a drug could start as a branded drug that had a valid patent, then change to a competitive brand that is a brand-name drug with a generic substitute. These drugs in 2006 were chosen using the PharmacyTimes.com[**] and Drugs.com websites.[††] PharmacyTimes.com is a website from the clinically based journal of the same name, which provides information for pharmacists. In

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[‡] Firms that take a finished drug product from a container in which it was distributed by the original manufacturer and place it into a different container without further manipulation of the drug. http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm434176.pdf

[§] http://www.redbook.com/redbook/online/

[**] http://www.PharmacyTimes.com

[††] http://www.Drugs.com

addition, it provides information for the top 200 most prescribed or 200 top-selling prescription drugs using IMS Health data. This is important, as IMS Health data[‡‡] captures 100 percent of the total U.S. pharmaceutical market for measuring sales at actual prices. Therefore, this enhances the validity of PharmacyTimes reports as a valuable and credible alternative to large fee-based prescription drug databases. In addition, I used Drugs.com to identify oncology drugs and control for any possible generic substitute.

As Figure 1 presents, after finalizing the top-selling brand and generic drugs for cancer, I combined observations for all states available in the 2006–2013 State Drug Utilization Data files, resulting in 126,390 records. I excluded the District of Columbia (DC) because almost all NDCs for DC did not match Food and Drug Administration data, and reported codes were not found on any websites. I excluded Arizona because no data were available for 2006–2009. I also removed observations with missing drug names and those that reported re-packagers as the manufacturer, because price setting for these drugs is different than for branded and regular generic drugs. Finally, after removing re-packagers, Arizona and DC, and all non-related and missing observations, I ended up with 124,663 records or 335 unique NDCs. This analysis is divided by manufacturer type (brand and generic).

**Generic Drugs**

Medicaid amount reimbursed per unit was used as a proxy for generic drug prices paid by Medicaid. After completing the list of oncology drugs, I computed each medication's price as

[‡‡] https://www.imshealth.com/files/web/IMSH%20Institute/NSP_Data_Brief-.pdf

Medicaid reimbursement amount divided by the total number of units for the NDC in each year, which I will refer to throughout as the Medicaid drug price. In other words, it is the amount Medicaid paid for each unit of a drug. The price of each NDC was averaged if multiple observations existed in the same year for each state. In other words, for each NDC in any given state, the Medicaid drug price was averaged for each year.

The equation below represents the basic structure that was used to estimate the changes in generic oncology drug prices after the ACA rebate increase.

$$Y_{it} = \beta_0 + \beta_1 MR_{it} + \beta_2 State + \beta_3 Year + Z_i + \varepsilon_{it} \quad (1)$$

In this model, *i* represents an NDC and *t* represents year. *Y* denotes the outcome measure, which is the Medicaid price for generic oncology drugs. To examine the effect of the Medicaid rebate increase on Medicaid drug prices, I used ordinary least squares (OLS) regression and excluded observations that reported a zero value for Medicaid drug price, as they represent the years before states started to cover a drug. *MR* is a dummy variable to represent the time of legislation (January 2010); it is 0 for the period prior to 2010 and 1 for 2010 and after. *State* is a categorical variable to reflect the state fixed effects. This controls for the differences in drug prices across states and any changes apart from the Medicaid rebate increase that may affect drug prices. I also used *Year* as a continuous variable to control for any secular increase in drug prices for a given year apart from inflation. *Z* is a vector of all other covariates that could affect the outcome such as package size, drug strength, coverage type, and drug formula. As previously mentioned, to control for package size, dosage form, and drug strength, I used Red Book and merged it with my database.

**Branded Drugs**

Instead of Medicaid drug price, I used WAC to estimate changes in competitive brand and branded drug prices for cancer drugs after the Medicaid rebate increase, as WAC is a good representation of what retail pharmacies actually pay for brand-name drugs.[64] In addition, unlike the Medicaid drug price, WAC is consistent across the states for a given year.

The equation below represents the basic structure of the model that I used to estimate the brand-name oncology drug price change after the ACA Medicaid rebate increase.

$$Y_{it} = \beta_0 + \beta_1 MR_{it} + \beta_2 Brand_i + \beta 3 (MR*Brand)_{it} + \beta_4 Year + Z_i + \varepsilon_{it} \quad (2)$$

In this model, *i* represents an NDC and *t* represents year. *Y* denotes the outcome measure, which is WAC for oncology drugs. To measure the effect of the Medicaid rebate increase on WAC, I applied OLS regression using the natural log of adjusted WAC as the outcome. As the WAC value for all branded drugs does not include zero, I chose OLS with a natural log. However, to address the smearing effect and take uncertainty in the retransformation factor into account, I applied Delta method to compute correct predicted values and standard errors.[69] *MR* is a dummy variable to represent the time of legislation (January 2010); it is 0 for the period prior to 2010 and 1 for 2010 and after. I used *Year* as a continuous variable to control for any secular increase in drug prices for a given year apart from inflation. However, I did not include the state fixed effects as in a given period WACs are consistent across all states. *Brand* is a dummy variable to represent branded or competitive brand drugs. It is 1 if it is a branded drug and 0 if it is a competitive brand. As I was interested to find the extent to which branded drug prices changed after the ACA, I used an interaction term

between *Brand* and *MR.* This estimate shows the extent to which oncology drug prices, by drug type, have changed after the ACA. In other words, I used marginal effects to predict actual drug prices for every combination of *MR* and *Brand.* I also controlled for other covariates that are listed for model 1.

All Medicaid drug prices and WACs were converted to inflation-adjusted 2013 dollars using the all-items Consumer Price Index (CPI). I used CPI all-items instead of CPI-drugs because it represents all goods and services purchased for consumption, including prescription drugs. In addition, the inability of CPI-drugs to properly adjust for quality and entry of new drugs reduces its precision. Therefore, I used the CPI all-items adjustment to have a better and more generalizable price representative.[70] Stata 12 was used to conduct all statistical analyses (StataCorp, College Station, TX).

## Results

### Sample Characteristics

The overall analytic sample included a total of 124,663 observations of top-selling oncology branded and generic drugs in 2006 that were followed through 2013. As Table 1 shows, these records represent 335 unique NDCs and a majority of them are parenteral (injectable). These observations represent 36 top-selling oncology drugs of which 25 are branded drugs and the rest are generics. Competitive brand drugs—those with generic substitutes—comprise 10 of the 25 top-selling branded drugs. Some people may be concerned that WAC is not an accurate indicator of drug prices purchased by prescribers; however, studies show that physicians usually purchase drugs at wholesale prices.[71,72]

Figure 3 represents the simple trend in WACs—adjusted for inflation—for all drugs without controlling for any other factors. The results show that average adjusted WACs for branded and competitive brand drugs were higher in post-period compared to pre-period.

Figure 4 represents the simple trend in average annual Medicaid drug prices—adjusted for inflation—for oncology drugs. The results show that average adjusted Medicaid prices did not increase for generic drugs in post-period compared to pre-period.

**The ACA Medicaid Rebate and Medicaid Prices for Generic Oncology Drugs**

Table 2 represents estimates of an OLS model using adjusted Medicaid reimbursement amount divided by the total number of units as the dependent variable. In other words, it shows the coefficient estimate from a dummy variable representing the implementation of the ACA in the regression model. Average annual price for each NDC was used in this analysis. The results show that after the implementation of the Medicaid rebate, average prices for generic oncology drugs increased by $28. Therefore, I find that the average price of top-selling generic anticancer drugs—adjusted for inflation—increased by $28 after the rebate increase.

The results also show that the average generic oncology drug prices under MCOs cost about $12 less than generic oncology drugs under FFS. Drug strength and year are strongly and negatively correlated with generic drug prices. A detailed table of all coefficients is presented in the appendix.

**The ACA Medicaid Rebate and Wholesale Acquisition Costs for Brand-Name Oncology Drugs**

Table 3 represents the coefficient estimates of an OLS model using natural log of adjusted wholesale acquisition costs as the dependent variable. As WAC is not an appropriate price indicator for generic oncology drugs, I excluded generic drugs from this analysis. The results show that after the ACA rebate provision in 2010, average WACs for all brand-name oncology drugs combined (branded and competitive brand) significantly increased by 2.4 percentage points, which is about $85, from $295 to $380. The results also show that oncology drug prices for a competitive brand are about 5.5 percentage points lower compared to brand-name drugs.

Table 4 represents predicted values of the coefficient estimate from the interaction variable representing brand-name drug prices, by type, after the implementation of the ACA Medicaid rebate in Table 3. In other words, I converted the coefficient estimates to a dollar value to show the extent to which drug prices have changed. The results show that after the implementation of the Medicaid rebate, average WACs for branded oncology drugs increased by $154, from $305 before the ACA to $459 after the implementation of the ACA Medicaid rebate. Also, for competitive brand oncology drugs, average WACs increased by $235, from $45 before the ACA to $280 after the implementation of the ACA Medicaid rebate. A detailed table of all coefficients is presented in the appendix.

## Discussion

The findings of this study demonstrate that the ACA Medicaid rebate increase was associated with significant increases in generic oncology drug prices measured by Medicaid

drug prices and oncology brand-name drug prices measured by WACs. The increase in oncology drug prices likely reflects the increases in the Medicaid rebate formula for both branded and generic drugs, from 15.1 to 23.1 percent of the AMP for branded drugs and from 11 to 13 percent for generic drugs. Therefore, a significant increase in drug prices after the Medicaid rebate increase can increase overall prescription drug costs paid by non-Medicaid payers via increasing WACs. As previously mentioned, because existing drug prices paid by non-Medicaid payers are used to set drug prices paid by Medicaid, any increase in drug prices, like WACs, could result in a higher pre-rebate reimbursement amount and overall prescription drug costs.

To my knowledge, this is the first study to estimate the association between the current Medicaid rebate and oncology drug prices while controlling for manufacturer type (brand or generic), package size, drug strength, availability of generic substitutes, coverage type, and state fixed effects. There are, however, a number of limitations to the analysis.

First, because all reported data are pre-rebate[§§] and federally mandated or state supplementary rebates are not publicly available, I used the payment per prescription presented in this study as a proxy for Medicaid prescription drug prices. This may result in overestimating to some degree the actual acquisition cost to Medicaid programs. However, the

[§§] Pre-rebate amount refers to the amount Medicaid reimbursed to pharmacies without considering the rebate amounts they receive from manufacturers. This is different than the actual drug prices paid by Medicaid, since Medicaid receives the rebate from manufacturers; because the rebates are confidential, it would be difficult to make any conclusion about the actual prices that Medicaid paid for each drug.

goal of this analysis is to examine the extent to which oncology drug prices have changed after the ACA.

Second, unlike WACs, Medicaid drug prices are specific to the Medicaid population, who make up about 20 percent of the U.S. population. The age and sex distributions for the Medicaid population are substantially different from the general U.S. population, with higher proportions of women and children. Therefore, other therapeutic classes may demonstrate different drug price changes than oncology drugs, because they may not be well represented among this population. However, this analysis measures WACs, which are consistent across payers for any given drug.

Third, as any outpatient prescription drug that states cover under either FFS or MCO could be used to assess the rebates, it is impossible to have a control group. Previously known inpatient drugs, which were exempted from the rebate, are now prescribed in physician offices, outpatient facilities, or nursing homes, and they would be counted as outpatient drugs. Therefore, under the new policy, almost all drugs are subjected to the Medicaid rebate. I could not find any drug that is exempted from the Medicaid rebate to use as a control group. Having no control group reduces the likelihood of drawing a causal effect.

Because I could not find an appropriate control group and there are other provisions under the ACA that may affect drug prices, it would be difficult to say that all increases in oncology drug prices are due to an increase in the Medicaid rebates. Although there were some hurdles in establishing causality between the Medicaid rebate increase and increases in drug price, I controlled for available factors that may have altered drug prices, excluding rebates,

AMPs, and best prices. Therefore, it may be reasonable to assume that the changes in drug prices are mostly due to the ACA, which is consistent and aligns with increases in the Medicaid rebates and the hypotheses. Even though I cannot establish causality between the Medicaid rebate increase and oncology drug prices, this study contributes to the literature because it is the only one that estimates the association between the increase in the Medicaid rebates under the ACA and oncology drug prices. Since 1997, no study has been conducted to measure the association between the Medicaid rebate and drug prices.

The results show that WACs increased more for competitive brand compared to branded oncology drugs after the ACA. A duopoly environment—when there are only two sellers—and marketing agreement between the brand and the generic manufacturers enable the brand manufacturer to continue pricing its branded product high after losing patent protection. Prior research has shown that brand-name manufacturers do not lower their prices in response to a generic entry;[73,74] however, having more generic entrants after patent expiration would significantly decrease generic drug prices.[75]

I performed several sensitivity checks. First, I used CPI-medical care instead of CPI all-items, and the results did not change. Using CPI-medical care, Medicaid price for generic and branded oncology drugs increased by \$42 ($p<0.01$). Also, WAC for branded and competitive brand oncology drugs increased by \$140 ($p<0.01$) and \$236 ($p<0.01$), respectively. Second, I limited the sample size to those branded drugs that did not go off-patent during the study period. The results show that WAC increased by \$44 ($p<0.01$), from \$474 to \$518 for branded oncology drugs. Third, I excluded observations that had a zero value for Medicaid drug prices.

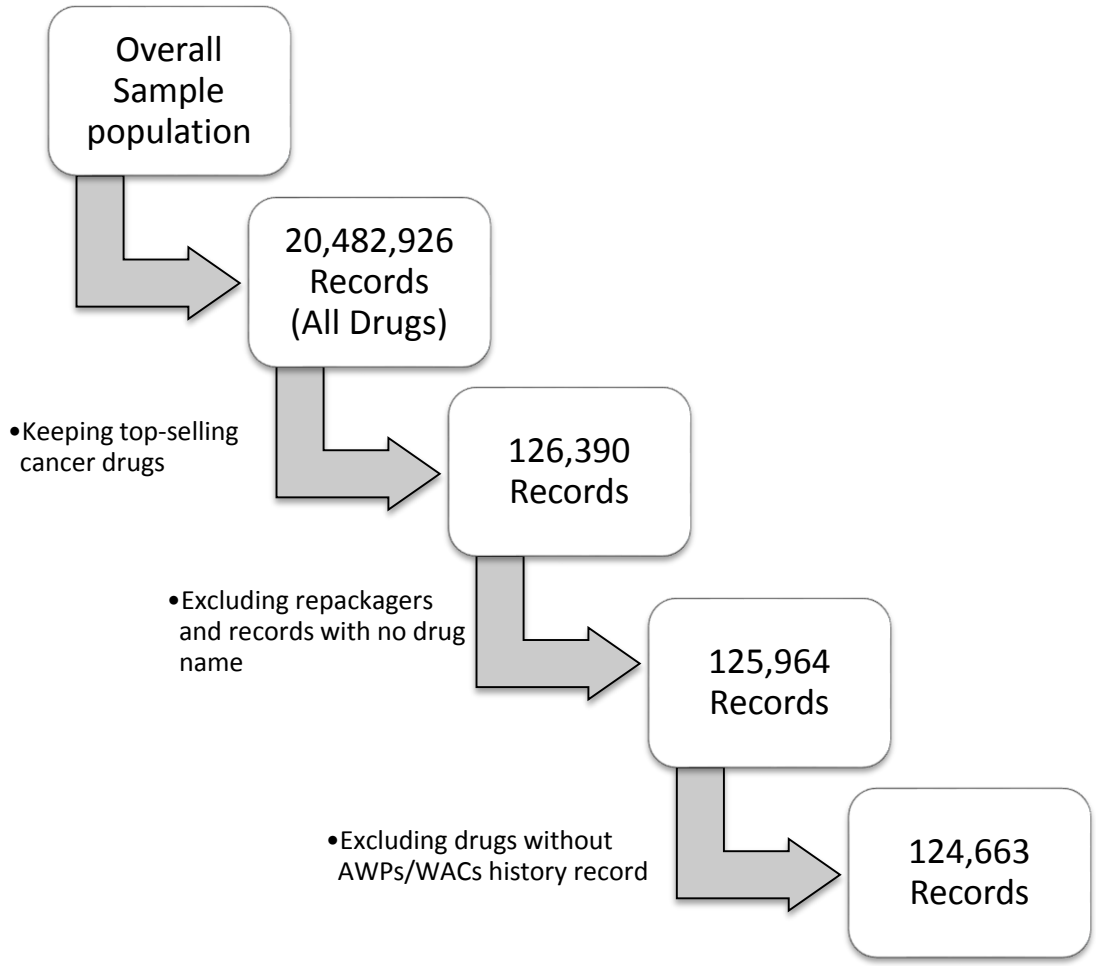
The results show that Medicaid price for generic oncology drugs increased by $37 ($p<0.01$), from $41.5 to $78.5. Lastly, I excluded the year 2010 because it might have taken a while for pharmaceutical firms to respond to this policy. The results show that for the competitive brand and branded oncology drugs, WAC increased by $257 ($p<0.01$) and $170 ($p<0.01$), respectively.

In sum, the findings from this study suggest that oncology drug prices have increased after the ACA. As expected, pharmaceutical companies increased their drug prices to offset costs associated with changes under the ACA, such as increases in rebate. However, it would be hard to estimate whether the government is paying more than it expects for the ACA, because rebate amounts are not available to researchers and the public.

The results of this paper could be of great interest to federal or state governments, advocates, and policymakers who are interested in bending the health care cost curve and having an efficient healthcare system. Although this study cannot reveal the actual acquisition cost of oncology drugs to Medicaid programs, it shows that pharmaceutical companies appear to have increased oncology drug prices to offset costs associated with increases in the rebate. Because the ACA will increase the number of insured consumers who receive drug benefits, increasing drug prices could undermine benefits of the ACA expansion; it could diminish drug adherence and effective utilization by affecting consumers' copays and out-of-pocket spending. Rising WACs for oncology drugs make these drugs expensive for other non-Medicaid insurers and private payers. Therefore, Medicaid drug procurement policies could have unintended impacts on drug prices and overall prescription drug expenditures by increasing drug prices paid by non-Medicaid payers. Although the Medicaid rebate helps state Medicaid programs to

generate revenues, any major change in drug prices would have a significant fiscal impact on states' budgets. The results of this paper can also help policymakers and state governments to have a deep understanding of the ACA impact on drug prices and draft efficient policies to control costs.

Figure 1: Selection Process of Medicaid State Drug Utilization Records



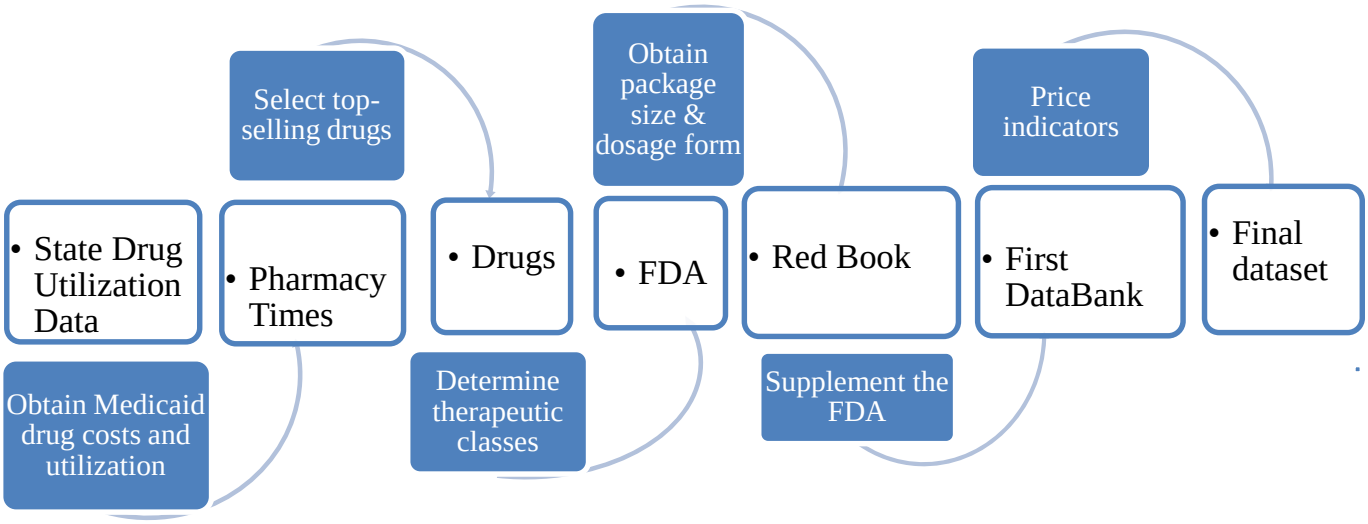



Figure 2: All Databases Used in This Analysis

Figure 3: Average Annual Wholesale Acquisition Costs by Manufacturer Type

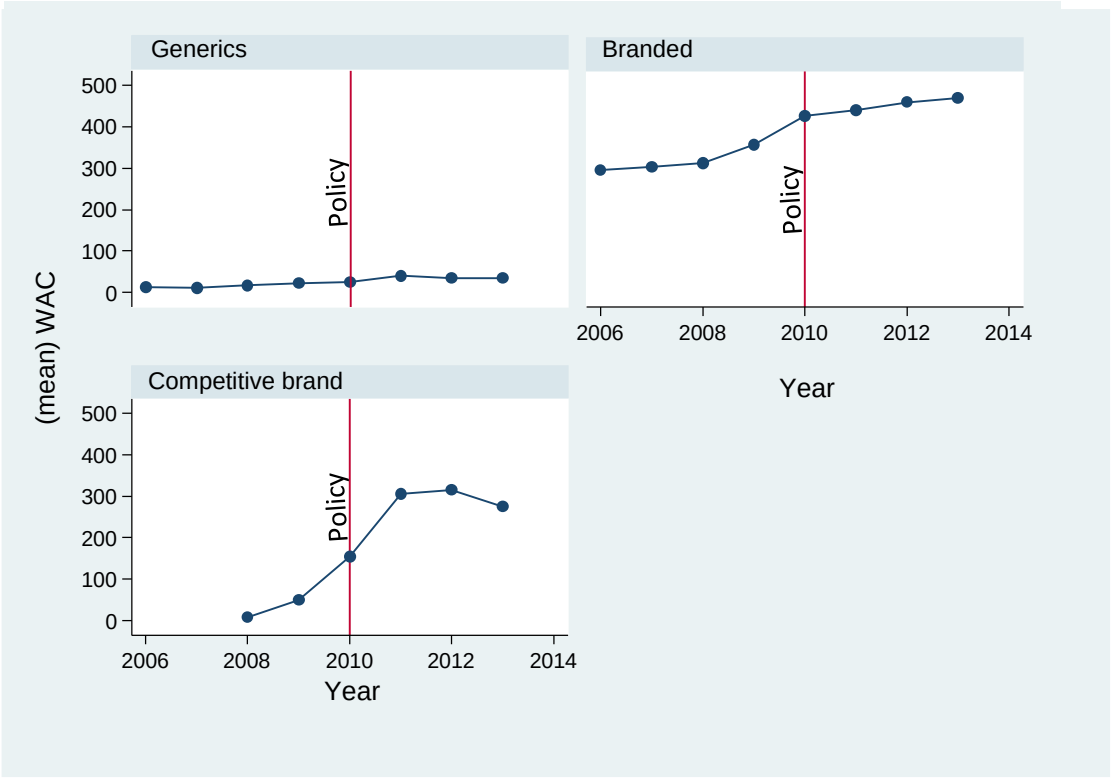


Figure 4: Average Annual Medicaid Drug Prices by Manufacturer Type

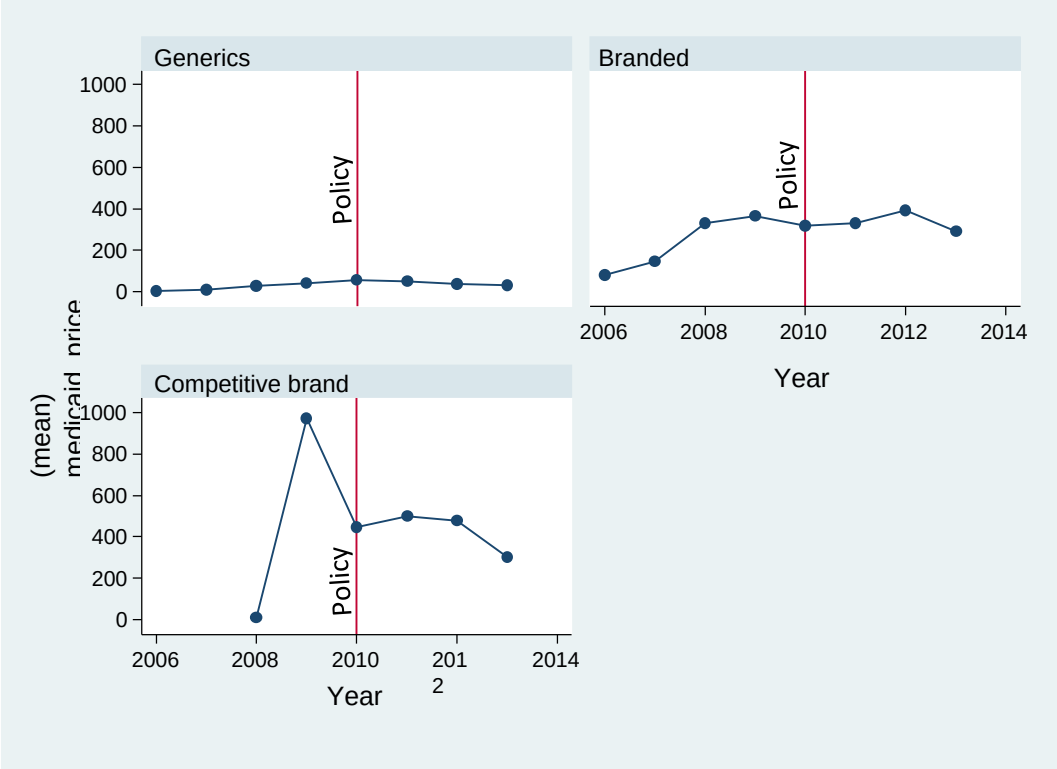


Table 1: Summary Statistics and Drugs Included in This Study

| Outcome | Number | | |
|---|---|---|---|
| Total number of records | 124,663 | | |
| Total number of unique NDCs | 335 | | |
| Dosage forms<br>Capsule<br>Tablet<br>Injection/powder<br>Cream | 36<br>69<br>227<br>3 | | |
| Number of drugs | 36 | | |
| | Generic | Brand | Competitive brand* |
| | 11 | 25 | 10 |

| | | |
|---|---|---|
| Herceptin ** | Velcade ** | Campath ** |
| Arimidex ** | Erbitux ** | Faslodex ** |
| Femara ** | Eloxatin ** | Sprycel ** |
| Xeloda ** | Gleevec ** | Alimta ** |
| Avastin ** | Rituxan ** | Casodex ** |
| Taxotere ** | Nexavar ** | Gemzar ** |
| Tarceva ** | Bexxar ** | Vectibix ** |
| Aromasin ** | Efudex ** | Hycamtin ** |
| Temodar ** | Doxorubicin | Thiotepa |
| Vinblastine | Vincristine | Amifostine |
| Carboplatin | Topotecan | Etoposide |
| Dactinomycin | Fludarabine | Tamoxifen |

*Number of branded drugs that have generic substitutes.

**Brand-name drugs (both branded and competitive brand drugs).

Table 2: Ordinary Least Squares Model Estimates of the Change in Generic Oncology Drug Prices After Medicaid Rebate Increase

| **Outcome** | **Estimates (SE)** |
|---|---|
| Program | 28.62** (12.58) |
| Type of payment (FFS)<br>Managed care | -11.86*** (3.908) |
| year | -8.715*** (2.944) |
| strength1 | -2.508** (1.105) |

*Note.* Base case scenario of each outcome measures is presented in parentheses.

**p<0.05. ***p<0.01.

Table 3: Ordinary Least Squares Model (Log-Linear) Estimates of the Change in WACs for Brand-Name Oncology Drugs After Medicaid Rebate Increase

| **Outcome** | **Estimates (SE)** |
|---|---|
| Target group<br>Program*Competitive Brand | -0.109*** (0.005) |
| Program | 0.0234*** (0.002) |
| Drug Type (Brand)<br>Competitive Brand | -0.535*** (0.005) |
| Type of payment (FFS)<br>Managed care | -0.004*** (0.001) |
| strength1 | 0.556*** (0.001) |
| year | 0.052*** (0.006) |

*Note.* Base case scenario of each outcome measure is presented in parentheses.

***p<0.01.

Table 4: Adjusted Estimates of WACs for Brand-Name Oncology Drugs After the ACA

| **Type of drug** | **Before** | **After** | **Difference** |
|---|---|---|---|
| Branded | $305 | $459 | $154*** |
| Competitive brand | $45 | $280 | $235*** |

***p<0.01.

## Chapter 3: The Impact of Medicare Part D on Racial Disparities in Drug Use, Coverage, and Expenditures Among Diabetics

### Summary

Prior to 2003, there were significant disparities in drug utilization and spending between Whites and minorities, particularly among seniors (individuals ≥65 years), and senior minorities spent less on and used fewer medications on average compared to Whites.[76-79] Medicare Part D was enacted under the Medicare Modernization Act of 2003 to reduce costs, increase efficiency, and increase access to prescription medications for seniors and disabled persons.[80-83] However, a unique feature of Part D prescription drug coverage is the so-called "doughnut hole,"[***] which can substantially increase out-of-pocket (OOP) spending for beneficiaries, especially those with higher utilization due to chronic diseases.[80-85] Among high drug utilizers who have chronic diseases, diabetic patients are prominent; diabetes is the seventh leading cause of death in the United States, with an annual cost of $245B.[86,87] Almost 60 percent of annual diabetes treatment costs (about $150B), could be prevented by increasing drug access.[87,88] Although diabetes is treatable, unequal access to prescription drugs and undiagnosed cases increase the risk of serious complications such as amputation, neuropathy, stroke, and nephropathy, which make diabetes an expensive disease to treat.[89-91]

It is presumed that better access to prescription drugs will reduce disease complications and annual diabetes costs.[89,92] However, it is unknown to what extent Medicare beneficiaries

[***] The gap in drug coverage in which Medicare beneficiaries are responsible for all of the costs.

with diabetes have been affected by the implementation of Medicare Part D. The purpose of this paper is to examine the impact of Medicare Part D on racial disparities in drug use, coverage, and expenditures among diabetics. This analysis is based on data from the 2001–2010 Medical Expenditure Panel Survey. These nationally representative data enable me to measure utilization, spending, and prescription drug coverage among beneficiaries with diabetes.[93]

## Introduction

Although Medicare was enacted under Title XVIII of the Social Security Act of 1965 to provide federally administered health insurance to individuals age 65 and older, regardless of income or medical history, it had limited outpatient prescription drug coverage for years.[94] Medicare Part D was enacted under the Medicare Modernization Act of 2003 to reduce costs, increase efficiency, and increase access to prescription medications for seniors and disabled persons.[95,96] Prior to Medicare Part D, Medicare health maintenance organizations, employer plans, Medigap, and Medicaid were the main sources of drug coverage.[97] There were significant discrepancies in drug utilization between Whites and minorities, particularly among seniors.[76-79] Although Part D was intended to reduce OOP spending and to increase access to prescription drugs for seniors, the existence of a coverage gap (the doughnut hole) can disproportionately increase OOP spending for beneficiaries from minority racial/ethnic groups relative to Whites, especially those with high prescription drug use.[80-85]

Prior research has shown that minorities spend less on and use fewer prescription drugs compared with Whites due to limited coverage or high drug costs.[78,98-101] It has also been shown that high OOP spending is associated with non-adherence to prescribed medicines; the likelihood of non-adherence is higher among beneficiaries with chronic diseases, especially those with diabetes.[76,79,83-85,102] Among chronic diseases, diabetes is important because it is the seventh leading cause of death in the United States; [86] 8.3 percent of the entire U.S. population (29 million people) and about 20 percent of senior populations were affected by diabetes in 2012. Also, about 86 million Americans age 20 and older had pre-diabetes in 2012.[103] Type II

diabetes accounts for about 95 percent of diabetes cases; approximately 40 percent of people with diabetes have three or more chronic conditions.[103-105] Average medical expenditures of people with diagnosed diabetes is about $13,700 per year, of which about $8,000 is attributed to diabetes.[103] Additionally, the burden of diabetes is disproportionately distributed among different ethnic groups, especially minorities.[106] Senior minorities with diabetes spent less on and used fewer medications on average compared with Whites,[77] while they had a higher diabetes prevalence, worse diabetes control, and higher diabetes complication rate compared to Whites.[107-112] Although diabetes is manageable and treatable, unequal access to prescription drugs, low medication adherence, and undiagnosed cases increase the risk of diabetes complications that make diabetes an expensive disease to treat.[89-90,91] The cost of diagnosed diabetes was $245 billion in 2012, of which $176 billion was attributable to direct medical costs and $69 billion was reduced productivity. Antidiabetic drugs only account for 12 percent of total direct costs, while inpatient care and treating diabetes complications account for more than 60 percent of the total cost.[87]

Although Medicare Part D aimed to increase access to prescription medicines and reduce seniors' OOP spending, uneven distribution of benefits among different racial groups can undermine the goal of Part D. Little is known about racial disparities in drug use, coverage, and expenditures among diabetics. To my knowledge, this study is the first that examines whether the implementation of Part D has affected racial disparities in drug use, coverage, and expenditures among diabetics.

## Literature Review

This section discusses prior research that has studied the impact of Medicare Part D on prescription drug utilization, OOP spending, and disparities. First, I review the recent literature relevant to the impact of Part D on Medicare spending. Then, I review the literature on the impact of Medicare Part D on prescription drug utilization and OOP spending. Finally, the last section reviews the literature on the effect of Medicare Part D on disparities in overall drug utilization and expenditures. This chapter concludes with a summary of findings and highlights literature gaps to emphasize the necessity for further research regarding the impact of Medicare Part D on racial disparities in drug utilization, coverage, and spending among diabetics.

### Medicare Expenditures

There is a general consensus in the literature that has examined the budgetary impact of Medicare Part D on Medicare overall expenditures. Using three different sources of data—the Medicare Provider Analysis and Review file, the Medicare Beneficiary file, and the Medicare Current Beneficiary Survey, and applying difference-in-differences methodology, Kaestner et al. found that Part D significantly reduced Medicare expenditures by 7 percent through an 8 percent decrease in the number of hospital admissions and a 12 percent decrease in total resource utilization.[113] Also, it has been shown that a $1 increase in prescription drug spending is associated with a $2.06 reduction in Medicare spending.[114] However, the existing literature measures the overall impact of Part D without stratifying the effect by disease category. Medicare expenditures could vary by type of disease (chronic or acute); this is important

because beneficiaries with more than three chronic conditions account for more than 70 percent of Medicare spending.[115] Medicare spending can be reduced, because these chronic conditions are mostly manageable with better access to prescribed medicines.

**Out-of-Pocket Spending and Drug Utilization**

Several studies have been conducted since the inception of Medicare Part D to examine the impact of Medicare Part D on drug utilization and OOP spending. Existing literature demonstrates that the introduction of Medicare Part D was associated with a reduction in OOP spending and an increase in drug utilization. Despite the fact that researchers used different secondary and primary databases and various time frames, the results are consistent: OOP spending was significantly reduced after Part D implementation, with the degree of reduction ranging from 18 to 49 percent. Prescription drug utilization increased by 5 to 32 percent among Medicare beneficiaries.[116-122] Studies have also shown that after the implementation of Part D, OOP spending decreased by $150 to $200 and the adjusted median number of prescriptions written annually increased by two to four prescriptions per patient year.[123,124] However, these studies were limited either in terms of time frame, type of data, an inadequate control group, or specific patient groups. Additionally, they did not evaluate the impact of Part D by type of disease, especially diabetes.

**Racial Disparities**

Despite the use of different databases, existing literature demonstrates that senior minorities had lower drug utilization and a higher rate of non-adherence compared to senior Whites. They show that minorities' drug utilization was 10 to 40 percent lower than Whites.[76-

[79,83] Furthermore, the literature shows that Part D has affected minorities disproportionately by increasing the disparity in annual prescription spending between African-Americans and Whites by $258, while it decreased disparities in a number of prescriptions filled and OOP spending between Hispanics and Whites by 2.9 prescriptions and $143, respectively.[125,126] On the other hand, a study by Chen et al.[127] found that following Medicare Part D, disparities in OOP spending and the probability of having unmet drug needs decreased for African-Americans and Hispanics, respectively, compared with their White counterparts. Although both studies used Medical Expenditure Panel Survey (MEPS) data, the results are different; Chen et al. used 2004—2007 data, whereas the other study used 2002–2009 data. Also, Chen et al. only included beneficiaries aged 65 and older in their analysis and had no control group; the other study included a control group and applied a different methodology, which was more thorough and accurate.

Using MEPS data, Hussein et al.[128] showed that Part D decreased the White–Hispanic disparity in overall adherence by 16 percentage points, while it increased White–Black disparity by 21 percentage points. Non-adherence to medicines due to high OOP is important because adherence to medicine is imperative for achieving therapeutic goals; poor adherence can have harmful consequences. Although adherence to medicines is not the focus of this study, current literature shows that the effect of Part D on adherence to medicines varied among different ethnic groups. This can impact disparities in utilization and spending because comorbid conditions, especially diabetes type II, can be easily managed and treated by improving adherence to medicines.[103]

Regarding drug coverage, the literature shows that Medicare Part D had no effect on the racial/ethnic disparity in drug coverage for African-Americans or Hispanics compared to White Medicare beneficiaries.[129] To my knowledge, the studies by Mahmoudi and colleagues are the only articles that measure the impact of Part D on racial disparities in OOP spending, drug coverage, and drug utilization among Medicare seniors. However, they measured aggregated racial disparities in drug use, drug coverage, and OOP spending among individuals who reported heart problems, diabetes, asthma, arthritis, or hypertension. The effect of Part D may differ for specific subgroups of Medicare beneficiaries because treatment pattern, prescription drug use, disease prevalence, and prescription drug costs are varied by type of disease. Although pulling different diseases together can increase the generalizability of results, it can also reduce its precision. This study specifically focuses on diabetic patients because diabetes is the seventh leading cause of death in the United States; it is a fast growing preventable chronic disease with an annual cost of $245B, and unequal access to prescription drugs can dramatically increase healthcare costs. In addition, I am using the MEPS data from 2001 to 2010, which provides a broader window to study the impact of Part D on racial disparities.

**Literature Gap**

The impact of Medicare Part D has been extensively studied since its inception. Generally, existing literature has shown that Medicare Part D helped Medicare beneficiaries by reducing OOP spending and enhancing access to prescription drugs. Also, it has shown that Medicare Part D has reduced Medicare overall expenditures. However, the impact of Medicare Part D on racial disparities has not been studied well. Although there are some studies that

evaluate the impact of Part D on drug utilization, coverage, and expenditures across different races, the existing literature does not examine the impact of Medicare Part D on racial disparity among patients with diabetes, because treatment pattern, prescription drug use, and disease prevalence are different from other chronic conditions. This study examines the extent to which Medicare Part D has affected racial disparities in prescription drug use, coverage, and expenditures among diabetics.

**Aims and Hypotheses**

Better access to prescription drugs can play an important role in controlling healthcare costs, especially among those with chronic diseases. Although Medicare Part D was aimed at reducing costs and increasing access to prescription medications, the existence of the doughnut hole can substantially affect OOP spending and access to prescription drugs for beneficiaries, especially those with high prescription drug use.

This study examines the impact of Medicare Part D on racial disparities in drug use, coverage, and expenditures among diabetics. The study considers whether disparities in prescription drug use, coverage, and spending have changed since Medicare Part D started in 2006. The specific aim of this study is to examine changes in prescription drug use, coverage, and spending after Medicare Part D for minority racial/ethnic groups compared to Whites. I hypothesize that disparities in drug use, expenditures, and drug coverage would decrease following Medicare Part D, because beneficiaries, especially minorities, would have better access to prescription drugs through Part D. Medicare Part D will reduce the gap between minorities and Whites in drug use, coverage, and expenditures.

**Conceptual Framework and Economic Theory**

Healthcare possesses uncertainties due to disease unpredictability and expensive health care services, including but not limited to prescription drugs, hospital care, and physician visits. Health insurance—including Medicare Part D coverage—increases access to care and reduces uncertainty for risk-averse individuals by assuring financial assistance in times of need. However, most insurance coverage plans require cost sharing. The purpose of cost sharing is to make individuals more conscious of health care costs and to reduce unnecessary health care utilization.[130]

Because individual factors, health service system factors, and social factors are the main characteristics that can enhance or impede health care utilization, I adopted the Andersen model[131] to measure the impact of Medicare Part D on diabetes drug use and expenditures. According to the Andersen model, health care consumption is determined by three elements: predisposing factors, enabling factors, and need. Diabetes type II, which is the dominant form of diabetes among seniors, is associated with age, gender, activity level, and eating habits.[132-134] I included age and gender as predisposing factors, because the risk of developing chronic diseases and healthcare utilization is associated with age, gender, activity level, and eating habits.[135,136] In general, older people have a tendency to use more medications because they have chronic conditions and their health deteriorates faster over time. I also included education as a social structure under predisposing factors because education plays a significant role in controlling diabetes complications.[137-139] It is presumed that educated people are more health conscious and have better eating habits compared to less educated people. In addition to

health insurance coverage for prescription drugs, I included social and economic resources such as income as an enabling factor because they facilitate the use of services. Need refers to the presence or severity of illness; I identified the number of chronic conditions for each individual to reflect the severity of disease.

People who are eligible for Part D are more inclined to use health care because, as an enabling factor, it allows individuals to fill their prescriptions and reduces their OOP spending. However, as mentioned earlier, diabetes prevalence and management, especially for type II, are correlated with gender, activity level, eating habits, and education level. Therefore, this analysis controls for gender, education, health status, marital status, and body mass index (an indicator of obesity) as predisposing factors. The number of comorbid conditions falls into the category of need, and this analysis controls for it. Also, this analysis controls for income, which is an enabling factor that can facilitate the use of services.

## Methods

### Data

This analysis is based on data from the 2001–2010 MEPS, conducted by the Agency for Healthcare Research and Quality. MEPS includes nationally representative samples of the noninstitutionalized population of the United States. It collects detailed information on health care expenditures and use of services, insurance coverage, sources of payment, health status, employment, and other sociodemographic characteristics.[93] In this study, I used the full-year consolidated data under the Household Component files, which include information on health status, demographic and socioeconomic characteristics, employment, access to care, and

satisfaction with health care. This was supplemented with data from the Medical Conditions and Prescribed Medicines files, which provide specific information about individuals' medical conditions and their prescriptions, including their insurance status, total expenditures, source of payment, OOP spending, and time of diagnosis.[140]

The sample for this analysis included all individuals 55 years of age and older who had diabetes. People were included if they responded affirmatively to a question asking whether they had ever been diagnosed with diabetes. The overall sample included a total of 10,537 MEPS respondents; 6,728 of them were 65 years of age and older and enrolled in Medicare Part D (the treatment group), and 3,809 were ages 55–64 and had no Medicare Part D coverage of any type (the comparison group). Because MEPS is not a perfect panel survey and does not follow the same individuals across the pre- and post-periods, I excluded individuals who were 64 at the beginning of the year, even though their age at the end of the year was 65, in order to prevent double counting.

Although the ideal comparison group would have been a group of seniors aged 65 and older who were not eligible for Part D, there is no such group. Like most previous studies,[121,123,141] I chose near-elderly adults aged 55–64 who had diabetes but no Medicare coverage as the comparison group. The rationale was that these individuals must have the same demand for medications as seniors because they had diabetes; however, their access to prescription drugs might be limited based on their health insurance plan.

**Variables**

During each round of MEPS, respondents were asked about the type of health insurance coverage they were enrolled in, such as Medicare, Medicaid, or a private insurance plan. They were also asked whether they had Medicare prescription drug benefit coverage, also known as Part D. Furthermore, for respondents who had at least one prescription medication purchase, MEPS asked whether they had a usual third-party payer for prescription medications, and if so, what type of payer. Respondents were classified as being enrolled in Medicare Part D coverage if they responded affirmatively to a question asking whether the person was covered by Medicare and covered by the prescription drug benefit.

During each round of MEPS, respondents were asked to provide the name of each prescription filled, the total and OOP cost of each prescription, and a list of the names, addresses, and types of pharmacies that filled prescriptions for their household. With each participant's consent, MEPS contacted the pharmacy to get detailed information on date filled, NDC, medication name, strength (amount and unit), quantity (package size and amount dispensed), and payments by source. If consent was not granted, the participant's self-reported information was used.

In this study, I examined disparities in prescription drug use, coverage, and spending among beneficiaries with diabetes by measuring annual drug expenditures, OOP spending, drug coverage, and the total number of prescriptions filled during the year. I measured the total number of prescriptions because the likelihood of having multiple comorbid conditions is higher among individuals aged 65 years and older, and people with comorbid conditions are more

likely to be taking nondiabetic medications.[142] In addition, diabetes can be controlled with appropriate diet and exercise, and beneficiaries may prioritize their drugs by filling prescriptions for other serious conditions. Therefore, measuring only the number of prescriptions associated with diabetes could not reveal racial disparity in drug utilization.

In this study, a minority is defined as anyone who is not reported as White, including African-Americans and Hispanics. Other ethnicities, including Asians, Indians, and Hawaiians, were excluded from this analysis because the goal of this study was to examine disparities in drug use, coverage, and expenditures between African-Americans and Whites and Hispanics and Whites with diabetes. In addition, literature suggests that Black–White and Hispanic–White disparities are a bigger problem for diabetes than disparities between Whites and other racial groups. Racial disparity is a difference in meeting health care needs, including treatment or access to care, between different racial/ethnic groups that is not justified by underlying health conditions.

**Analytic Strategy**

The basic approach is to (a) examine changes in prescription drug utilization and spending before and after the implementation of Medicare Part D for the treatment group by race; and (b) compare these changes to near-elderly adults to determine whether the changes were due to Medicare Part D or other factors. I adopted a difference-in-difference-in-differences (DDD) methodology to estimate the impact of Part D on racial disparities in drug use, coverage, and expenditures among diabetics. Using a DDD model, I estimated drug use, coverage, and expenditures among diabetics by race before and after Part D. Then, I measured

the extent to which drug use, coverage, and expenditures changed between African-Americans and Whites and Hispanics and Whites.

The model compared differences in outcomes before and after 2006 for diabetic seniors who had Medicare Part D coverage with near-elderly diabetic adults who had no Medicare Part D coverage of any type. As earlier mentioned, individuals were included if they responded affirmatively to a question asking whether they had ever been diagnosed with diabetes. In other words, I compared seniors aged 65 and older to adults aged 55–64 who did not have prescription drug coverage through Medicare to find the extent to which diabetes drug use and expenditures have changed after the implementation of Medicare Part D.

The methodology assessed the impact of Medicare Part D by comparing changes in utilization and spending for Part D beneficiaries by race before and after 2006 to changes for the comparison group. DDD analysis is acceptable if both the Part D and comparison groups would have experienced similar trends in diabetes drug use and expenditures in the absence of Medicare Part D. To test trend similarity in pre-period, I compared unadjusted differences between Whites and African-Americans and between Whites and Hispanics for aforementioned measures from 2001 to 2005. As shown in Table 1, there is not a significant difference in annual drug expenditures, OOP spending, drug coverage, and the total number of prescriptions between seniors and near-elderly adults during this time period. The regression-based DDD methodology further controls for other differences between the treatment and the comparison groups that may affect utilization and spending, including sex, education, poverty level, state fixed effects, marital status, comorbidity, obesity, and perceived health status.

The equation below represents the basic structure of the DDD model that I used to estimate the impact of Part D on diabetes drug use and expenditures.

$$Y_i = \beta_0 + \beta_1 Race_i + \beta_2 MMA_i + \beta_3 Senior_i + \beta_4 (Race * MMA)_i + \beta_5 (Race * Senior)_i + \beta_6 (Senior * MMA)_i + \beta_7 (Senior * Race * MMA)_i + Z_i + \varepsilon_i \quad (1)$$

In this model, *i* represents an individual. *Y* denotes outcome measures, which are the total number of prescription drugs, OOP spending, prescription drug coverage, and annual drug expenditures. *Race* is a categorical variable, and Whites are set as the reference group. *Race*=1 represents African-Americans and *Race*=2 represents Hispanics. *MMA* is a binary vector of time when Medicare Part D implemented. It is 1 if individuals were surveyed after 2006; otherwise, it is 0. As I mentioned earlier, I excluded individuals who were 64 at the beginning of the year, even though their age was reported as 65, in order to prevent double counting. *Senior* is a dummy variable representing the treatment and the comparison group. It is 1 if they are 65 years or older (the treatment group); otherwise, it is 0 (the comparison group). I have several interaction terms between race and the time the survey was conducted, between being a senior and the time the survey was conducted, and between being a senior and race. My estimate of interest is the variable with triple interactions, $\beta_7$. The estimate of this variable shows the extent to which Medicare Part D has affected drug use, coverage, and expenditures among beneficiaries with diabetes stratified by race. My broad approach was to estimate individual regressions for each treatment and comparison group and then use the estimated model to predict the mean level of aforementioned outcomes for African-Americans, Hispanics, and Whites. I estimated a pre-MMA regression and predict the conditional mean level of

outcomes for African-Americans, Hispanics, and Whites, holding other characteristics constant. I then estimated a post-MMA regression and used it to generate the predicted mean level of outcomes for African-Americans, Hispanics, and Whites. Instead of multiplicative effects, which is interpreting the estimated coefficients, I used marginal effects to predict actual expenditures and utilization for every combination of *Race, Senior,* and *MMA.* The significance of marginal effects represented in Table 8 is different than the multiplicative effects represented in Tables 4–7 because reported effects in Table 8 are relative to the baseline estimates in their own category.[†††] Marginal effects represented in Table 8 control for differences between the groups in baseline effects. Also, because the model is in log format, retransforming the estimates to their actual values would affect associated standard errors. I did not use means of covariates for making prediction because mean of retransformations does not equal retransformation of mean.[‡‡‡]

*Z* is a vector of all other covariates that could affect outcomes such as education, poverty level, comorbidity, obesity, perceived health status, state fixed effects, marital status, and sex. *Education* is a categorical variable. *Education*=1 represents less than 12 years of education, *education*=2 represents 12 years of education, and *education*=3 represents higher education. *Poverty level* is a categorical variable. *Poverty*=1 represents poor or near poor (<125% federal poverty level [FPL]), *poverty*=2 represents low income (125-200% FPL),

[†††] http://www.maartenbuis.nl/publications/interactions.pdf

[‡‡‡]http://www.uphs.upenn.edu/dgimhsr/documents/costanalysis.sp14.pdf

*poverty*=3 represents middle income (200-400% FPL), and *poverty*=4 represents high income (>400% FPL). Comorbidity is a categorical variable. *Comorbidity*=1 represents no comorbid condition, *comorbidity* =2 represents one comorbid condition, *comorbidity* =3 represents two comorbid conditions, and *comorbidity* =4 represents three or more comorbid conditions. *Obesity* is a categorical variable that is defined based on body mass index. *Obesity*=1 represents underweight people, *Obesity*=2 represents normal people, *Obesity*=3 represents overweight people, and *Obesity*=4 represents obese people. *Health* is a categorical variable that represents perceived health status. *Health* =1 represents poor health status, *Health* =2 represents fair health status, *Health* =3 represents good health status, and *Health* =4 represents very good and excellent health status.

Serial correlation is one of the biggest problems in the DDD method that can undermine the validity of estimates.[143] I aggregated the data into two groups: pre- and post-intervention. Creating two intervention groups reduced the likelihood of serial correlation among observations. To measure the impact of Part D on prescription drug utilization, I applied the generalized linear model (GLM) because some observations had zero prescription drugs and the distribution of prescription drugs was heavily skewed to the right. Using GLM allows accounting for a response variable that has nonstandard distribution and correctly measures the number of prescriptions without assuming that the drug utilization values are normally distributed. I chose a GLM with a log link and gamma distribution for total drug expenditures and OOP spending and a GLM with a log link and negative binomial distribution for the total number of prescriptions. I chose GLM with a log link and gamma distribution because expenditures are continuous but nonnormal. Using GLM allowed me to account for a response variable that had

nonstandard distribution and correctly counted the number of prescriptions without assuming drug utilization values were normally distributed. For utilization, I chose GLM with a log link and negative binomial distribution over Poisson distribution, because Poisson distribution assumes that the mean and variance are the same; however, the dataset showed that variances of outcomes were greater that than the means. For prescription drug coverage, I fit a logistic regression because the outcome was binary.

All drug expenditures and OOP spending were converted to inflation-adjusted 2010 dollars using the all-items CPI. I used CPI all-items instead of CPI-drugs because it represents all goods and services purchased for consumption including prescription drugs. Although CPI all-items does not reflect price inflation specific to drugs, the inability of CPI-drugs to properly adjust for quality and entry of new drugs reduces its precision. Therefore, I used the CPI all-items adjustment to have a better and more generalizable price representative.[144]

I used sampling weights, strata, and the primary sampling unit provided in MEPS to account for differential selection probabilities, to adjust for nonresponses, to control for design effects, and to generate appropriate standard errors to reflect a nationally representative sample of the noninstitutionalized civilian U.S. population. Stata 12 was used to conduct all statistical analyses (StataCorp, College Station, TX).

# Results

## Study Population Characteristics

Table 2 provides descriptive statistics for diabetic seniors and near-elderly adults. The overall sample includes a total of 10,154 MEPS respondents who were diagnosed with diabetes, 6,428 of whom were in the treatment group and 3,726 of whom were in the comparison group. Within the treatment group, there were 2,784 and 3,644 individuals who were surveyed in pre- and post-periods, respectively. Within the comparison group, there were 1,504 and 2,222 individuals who were surveyed in pre- and post-periods, respectively. The average age of the treatment group was 74.5, whereas it was about 60 for the comparison group. About 60 percent of the treatment group had at least 12 years of education, whereas about 76 percent of the comparison group had at least 12 years of education. About 45 percent of the treatment group and 49 percent of the comparison group were male. More than 35 percent of people in both the treatment and the comparison group reported poor or fair health status.

## Unadjusted Estimates of Prescription Drug Spending and Utilization

Table 3 demonstrates the simple means and percentages for total drug expenditures, OOP spending, prescription drug coverage, and the total number of prescription drugs. The results show that total drug expenditures for Medicare Part D beneficiaries increased by $518, from $3,308 before Part D to $3,826 after the implementation of Part D. There was no statistically significant change in total prescription drug spending for the comparison group. The results also show that OOP spending decreased among the treatment group by $689, from

$1,642 before Part D to $953 after the implementation of Part D. In addition, OOP spending significantly decreased for the comparison group.

The total number of prescriptions per person (including refills) that were filled by seniors increased from 47.6 before Part D to 50.4 prescriptions after the implementation of Part D. There was no statistically significant change in total prescription drug spending for the comparison group. However, prescription drug coverage significantly increased only for the treatment group, from 36 percent before Part D to 74 percent after the implementation of Part D.

**Impact of Part D**

In Equation 1, I examined annual drug expenditures, OOP spending, prescription drug coverage, and the total number of prescriptions between African-Americans and Whites, and between Hispanics and Whites. Tables 4–7 represent coefficients of Equation 1 in a log-linear format for annual drug expenditures, OOP spending, the total number of prescription drugs, and drug coverage, respectively. The results show that education and income are negatively associated with diabetes drug use and expenditures. For instance, Medicare beneficiaries who had higher education and income spent less on diabetes drugs compared to poor and less educated individuals. As previously mentioned, I used marginal effects to predict actual expenditures and utilization for every combination of *Race, Senior,* and *MMA.*

Table 8 reports marginal effects of the impact of Part D on annual drug expenditures, OOP spending, the total number of prescriptions, and drug coverage between African-Americans and Whites, and between Hispanics and Whites, in terms of actual dollar value, the

number of prescriptions, and prescription drug coverage. These are adjusted predictions for $B_7$ in the model and have been calculated for both the treatment and the comparison groups before and after Part D. The difference reflects the net change in utilization and expenditures in the treatment group relative to the comparison group.

Between African-Americans and Whites, the results show that Part D insignificantly increased disparities in annual drug expenditures by $446. In other words, Part D insignificantly increased the gap in total drug expenditures between African-Americans and Whites. On the other hand, Part D insignificantly decreased disparities in OOP spending and the total number of prescription drugs by $82 and 4.2 prescriptions, respectively. However, the results show that Part D significantly reduced the racial/ethnic disparity in drug coverage by 15 percent for African-Americans compared to White Medicare beneficiaries.

Between Hispanics and Whites, the results show that Part D insignificantly decreased the disparity in annual drug expenditures and OOP spending by $397 and $286, respectively. In other words, Part D insignificantly decreased the gap in total drug expenditures and OOP spending between Hispanics and Whites. However, Part D significantly decreased disparities in the total number of prescription drugs and drug coverage by 8.6 (<0.05) prescriptions and 25 percent for Hispanics compared to White Medicare beneficiaries.

## Discussion

The findings demonstrate that the introduction of Medicare Part D reduced racial disparities in drug use, coverage, and spending among diabetic beneficiaries, but the effect was not distributed equally among minorities. In other words, when the effect was stratified by

race, the results show Part D significantly reduced disparity in drug coverage without having a significant impact on the disparities in OOP spending and the total number of prescription drugs between African-Americans and Whites. However, it shows that Part D significantly decreased the disparities in the total number of prescription drugs and drug coverage between Hispanics and Whites.

Reduction in diabetes drug use implies that the gap in filling prescription drugs was broadened between minorities and Whites. This could happen due to the existence of the doughnut hole that could disproportionately impact individuals. Because the majority of diabetic individuals are at particularly high risk of reaching the doughnut hole due to diabetes drug expenditures and multiple chronic conditions, those who have a higher income are more prone to fill their prescriptions.[84,85] Even though Part D provides access to care for seniors, Medicare beneficiaries could be disproportionately affected by their income.

Although Medicare Part D significantly reduced overall OOP spending, it only reduced racial disparities in drug use for Hispanics with diabetes. One explanation may be that Hispanics have a higher rate of enrollment in Medicare Advantage plans that have drug coverage, as opposed to stand-alone drug plans. This is explained in detail in limitations. Those who face the doughnut hole are less likely to adhere to their medication, especially if they are poor, since they have to pay 100 percent of all drug costs. Medicare Part D was intended to increase access to prescription drugs and improve seniors' health while saving money; however, unintended consequences like lack of adherence to diabetes medicines increase federal government

expenditures because untreated patients are more likely to have complications such as amputations or severe renal diseases.

To my knowledge, this is the first study to examine the impact of Medicare Part D on racial disparities in utilization, drug coverage, and spending among beneficiaries with diabetes. There are, however, a number of limitations to the analysis.

First, the ideal comparison group would have been a group of seniors aged 65 and older who were not eligible for Part D. Unfortunately, there is no such group. As most previous studies have done,[121,123,141] I chose near-elderly adults aged 55–64 who had diabetes but not Medicare as the comparison group. Although they may be different from seniors without Medicare Part D in terms of disease severity and comorbid condition, I controlled for these covariates in the analysis. This makes the comparison group almost equal and comparable to the treatment group. Second, Medicare beneficiaries could receive their drug insurance coverage through stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. PDPs only cover drug expenditures, while MA-PDs cover all Medicare benefits including drugs. These two different plans could have different impacts on beneficiaries' OOP spending. Unfortunately, I was not able to differentiate plans' impact with the MEPS data. Third, diabetes treatment and medications are different for each type of diabetes. People with type II diabetes are more likely to take non-insulin medications to control their blood sugar, whereas insulin is critical for type I diabetes. In other words, diabetes, especially type II, can be controlled with appropriate diet and exercise, and beneficiaries may prioritize their drugs by filling prescriptions for other serious conditions. Therefore, I expect the

effect of Part D on utilization and spending be greater among type II diabetics. However, MEPS does not provide information on the type of diabetes. Fourth, participants in MEPS are surveyed apart from their U.S. residency status. Because the only effect is on utilization among Hispanics, this may be attributed to undocumented and illegal Hispanics who may have participated in MEPS. I tried to identify individuals' residency status; however, no data is available on people's citizenship status prior to 2007. Although there was no way to identify non-resident Hispanics among the comparison group, I only included people who had Medicare and were 65 years of age and older in the treatment group. This at least controlled for citizenship status among the treatment group because they had Medicare. Finally, lack of information about disease severity, physician–patient relationships, cultural factors, and patients' preferences, which could vary across different racial/ethnic groups, limited my ability to accurately measure racial differences in drug utilization and OOP spending.

In sum, the findings from this study suggest that Medicare Part D appears to be helpful in reducing disparities in drug use and coverage among diabetics. However, as the results show, the effect was significant among Hispanics.

The results of this paper could be of great interest to federal or state governments, advocates, and policymakers who are interested in an equitable healthcare system. Part D is designed to increase coverage and access to drugs for all seniors; the results of this study show the extent to which benefits of Part D are distributed among seniors with diabetes. These results will help policymakers or federal officials to draft policies that reduce OOP spending specifically for minorities who have diabetes. Also, policymakers can promote a discounted

program to cover drugs for diabetic minorities 65 years of age and older who may reach the doughnut hole. In addition, they can take steps toward improving adherence to medicines because the lack of adherence can eventually increase health care system costs. In general, investing in supplementary programs besides Part D to reduce the financial burdens of diabetes, especially for minorities, could result in a long-term saving because minorities are not benefited compared to Whites.

Table 1: Trends in the Unadjusted Differences Between Whites and Minorities, Between Whites and African-Americans, and Between Whites and Hispanics, Who Had Diabetes Prior to the Implementation of Part D

| Outcome measure | Difference between two groups 2001-2003 | Difference between two groups 2004-2005 | Difference over time† | DDD‡ | t(p-value) |
|---|---|---|---|---|---|
| | Whites *vs.* African-Americans | | | | |
| **Annual Drug Expenditures** | | | | | |
| Part D (>65)<br>Comparison (55-64) | $160.5<br>-$61.6 | $170.5<br>$69.6 | $10.0<br>$131.2 | -$121.2 | 0.03(0.85) |
| **Rx OOP spending** | | | | | |
| Part D (>65)<br>Comparison (55-64) | $407.5<br>-$48.9 | $402.4<br>$336.2 | -$5.1<br>$385.1 | -$390.2 | 1.43(0.23) |
| **Total number of Rx** | | | | | |
| Part D (>65)<br>Comparison (55-64) | -0.90<br>-5.33 | -1.81<br>-6.20 | -1.71<br>-0.87 | -0.85 | 0.01(0.91) |
| **Drug Coverage** | | | | | |
| Part D (>65)<br>Comparison (55-64) | 0.09<br>0.20 | 0.14<br>0.24 | 0.05<br>0.04 | 0.01 | 0.00(0.99) |
| | Whites *vs.* Hispanics | | | | |
| **Annual Drug Expenditures** | | | | | |
| Part D (>65)<br>Comparison (55-64) | $855.0<br>$718.6 | $752.2<br>$752.4 | -$102.8<br>$33.8 | -$136.6 | 0.07(0.79) |
| **Rx OOP spending** | | | | | |
| Part D (>65)<br>Comparison (55-64) | $459.9<br>$72.0 | $607.1<br>$204.1 | $147.2<br>$132.1 | $15.1 | 0.00(0.96) |
| **Total number of Rx** | | | | | |
| Part D (>65)<br>Comparison (55-64) | 11.1<br>7.81 | 9.43<br>5.23 | -1.64<br>-2.58 | 0.94 | 0.03(0.86) |
| **Drug Coverage** | | | | | |
| Part D (>65)<br>Comparison (55-64) | 0.22<br>0.31 | 0.18<br>0.30 | -0.04<br>-0.01 | -0.03 | 0.06(0.80) |

*Sources:* Author's analysis of data from the Medical Expenditure Panel Surveys, Household Component, 2001–10.

† Represents the difference of difference between White and minority before and after the MMA.

‡ Represents the difference between seniors and near-elderly.

Table 2: Percentage Distribution of Demographic Characteristics of the Medical Expenditure Panel Survey Sample Who Had Diabetes by Target Group

| Characteristics | All Respondents (N=10,154) % | |
|---|---|---|
| | Part D N=6,428 | Comparison N=3,726 |
| **Age** | 74.5*** | 59.4 |
| **Education** | | |
| Less than high school | 34.7*** | 22.2 |
| High school graduate | 33.3 | 34.6 |
| Some college or more | 32.0*** | 45.2 |
| **Sex** | | |
| Male | 45.8*** | 50.6 |
| Female | 54.2*** | 49.4 |
| **Poverty level** | | |
| Poor/Near Poor (x<150% FPL) | 20.3*** | 14.9 |
| Low income (150% FPL<x<200% FPL) | 20.6*** | 10.8 |
| Middle income (200% FPL<x<400% FPL) | 30.5* | 28.6 |
| High income (400% FPL<x) | 28.6*** | 45.7 |
| **Race/Ethnicity** | | |
| Non-Hispanic White | 74.9*** | 71.1 |
| Non-Hispanic Black | 13.5** | 15.1 |
| Hispanic | 11.5*** | 13.8 |
| **Health status** | | |
| Excellent & Very Good | 24.5 | 25.4 |
| Good | 35.0*** | 38.5 |
| Fair | 27.7** | 25.1 |
| Poor | 12.8** | 11.0 |
| **Marital status** | | |
| Married | 52.6*** | 68.0 |
| Not married | 47.4*** | 32.0 |

*Sources:* Author's analysis of data from the Medical Expenditure Panel Surveys, Household Component, 2001–10.

*Notes:* Treatment group is adults aged 65 years and older who had Medicare drug benefit and were diabetic. The comparison group is adults aged 55–64 years who had diabetes but had no Medicare drug benefit.

*The mean of this variable differs significantly between the comparison and treatment group at the alpha = .1 level. **Difference is statistically significant at 0.05 level. ***Difference is statistically significant at 0.01 level.

Table 3: Unadjusted Outcomes Among Diabetics by Target Group Before and After Part D

| Outcomes | All Respondents (N=10,154) | | | |
|---|---|---|---|---|
| | Part D (N=6,428) | | Comparison (N=3,726) | |
| | Before MMA | After MMA | Before MMA | After MMA |
| **Annual drug expenditures** | | $3,826*** | | |
| White | $3,308 | $3,945*** | $3,193 | $3,272 |
| AA | $3,431 | $3,575 | $3,315 | $3,424 |
| Hispanic | $3,278 | $3,320*** | $3,254 | $3,323 |
| | $2,415 | | $2,537 | $2,410 |
| **OOP spending** | $1,642 | $953*** | $1,138 | $867*** |
| White | $1,763 | $1,032*** | $1,184 | $934** |
| AA | $1,365 | $710*** | $1,028 | $713*** |
| Hispanic | $1,229 | $709*** | $1,028 | $685*** |
| **Total number of Rx** | 47.6 | 50.4** | 41.0 | 40.7 |
| White | 48.8 | 50.7 | 41.1 | 41.8 |
| AA | 49.9 | 50.3 | 46.6 | 40.5* |
| Hispanic | 38.4 | 47.9*** | 34.4 | 34.6 |
| **Drug Coverage** | 0.36 | 0.74*** | 0.73 | 0.72 |
| White | 0.40 | 0.72*** | 0.81 | 0.78 |
| AA | 0.28 | 0.77*** | 0.59 | 0.58 |
| Hispanic | 0.19 | 0.86*** | 0.50 | 0.52 |

*Sources:* Author's analysis of data from the Medical Expenditure Panel Surveys, Household Component, 2001–10.

*Notes:* Treatment group is adults aged 65 years and older who had Medicare drug benefit and were diabetic. The comparison group is adults aged 55–64 years who had diabetes but had no Medicare drug benefit.

*The mean of this variable differs significantly between the comparison and treatment group at the alpha = .1 level. **Difference is statistically significant at 0.05 level. ***Difference is statistically significant at 0.01 level.

Table 4: Difference-in-Difference-in-Differences Coefficients of the Impact of Part D on Racial Disparity in Annual Drug Expenditures Among Diabetics

| Outcome Measures | Coefficient (SE) |
|---|---|
| **Target Population** | |
| African-American*MMA*Senior | -0.132 (0.12) |
| Hispanic* MMA *Senior | 0.142 (0.13) |
| **Poverty (poor)** | |
| Low income | -0.108** (0.04) |
| Middle income | -0.068* (0.038) |
| High income | 0.001 (0.04) |
| **Education (<diploma)** | |
| Diploma | 0.018 (0.031) |
| College | 0.11*** (0.034) |
| **Health status (poor)** | |
| Fair | -0.26*** (0.040) |
| Good | -0.44*** (0.044) |
| Very Good & Excellent | -0.64*** (0.044) |
| **Sex (Male)** | |
| Female | 0.126*** (0.026) |
| **MMA** | 0.121* (0.064) |
| **Senior** | 0.093* (0.056) |

*Note.* Base case scenario of each outcome measure is presented in parentheses.

*p< 0.1. **p< 0.05. ***p< 0.01.

Table 5: Difference-in-Difference-in-Differences Coefficients of the Impact of Part D on Racial Disparity in Diabetes OOP Spending Among Diabetics

| Outcome Measures | Coefficient (SE) |
|---|---|
| **Target Population** | |
| African-American*MMA*Senior | -0.078 (0.16) |
| Hispanic* MMA *Senior | 0.093 (0.19) |
| **Poverty (poor)** | |
| Low income | 0.064 (0.05) |
| Middle income | 0.079* (0.048) |
| High income | 0.113** (0.053) |
| **Education (<diploma)** | |
| Diploma | 0.049 (0.038) |
| College | 0.118*** (0.043) |
| **Health status (poor)** | |
| Fair | -0.15**0 (0.048) |
| Good | -0.25*** (0.048) |
| Very Good & Excellent | -0.46*** (0.05) |
| **Sex (Male)** | |
| Female | 0.23***(0.033) |
| **MMA** | -0.129 (0.092) |
| **Senior** | 0.350*** (0.075) |

*Note.* Base case scenario of each outcome measure is presented in parentheses.

*p<0.1. **p<0.05. ***p<0.01.

Table 6: Difference-in-Difference-in-Differences Coefficients of the Impact of Part D on Racial Disparity in Total Number of Prescriptions Among Diabetics

| Outcome Measures | Coefficient (SE) |
|---|---|
| **Target Population** | |
| African-American*MMA*Senior | 0.084 (0.092) |
| Hispanic*MMA*Senior | 0.132 (0.091) |
| **Poverty (poor)** | |
| Low income | -0.032 (0.026) |
| Middle income | -0.070*** (0.024) |
| High income | -0.084*** (0.027) |
| **Education (< diploma)** | |
| Diploma | -0.041* (0.021) |
| College | -0.023 (0.024) |
| **Health status (poor)** | |
| Fair | -0.23*** (0.027) |
| Good | -0.41*** (0.027) |
| Very Good & Excellent | -0.56*** (0.030) |
| **Sex (Male)** | |
| Female | 0.126*** (0.018) |
| **MMA** | 0.111*** (0.036) |
| **Senior** | 0.160*** (0.034) |

*Note.* Base case scenario of each outcome measure is presented in parentheses.

*p<0.1. **p<0.05. ***p< 0.01.

Table 7: Difference-in-Difference-in-Differences Coefficients of the Impact of Part D on Racial Disparity in Prescription Drug Coverage Among Diabetics

| Outcome Measures | Coefficient (SE) |
|---|---|
| **Target Population** | |
| African-American*MMA*Senior | 2.32*** (0.65) |
| Hispanic*MMA*Senior | 8.19*** (2.42) |
| **Poverty (poor)** | |
| Low income | 1.37*** (0.12) |
| Middle income | 2.26*** (0.18) |
| High income | 3.77*** (0.35) |
| **Education (< diploma)** | |
| Diploma | 1.39*** (0.10) |
| College | 1.33*** (0.10) |
| **Health status (poor)** | |
| Fair | 1.29** (0.12) |
| Good | 1.57*** (0.15) |
| Very Good & Excellent | 1.47*** (0.16) |
| **Sex (Male)** | |
| Female | 1.07 (0.066) |
| **MMA** | 0.86 (0.109) |
| **Senior** | 0.184*** (0.022) |

*Note.* Base case scenario of each outcome measure is presented in parentheses.

*p< 0.1. **p< 0.05. ***p< 0.01.

Table 8: Difference-in-Difference-in-Differences Estimates of the Impact of Part D on OOP Spending, Drug Coverage, and the Total Number of Prescriptions Among Diabetics

| Outcome measures | Whites *vs.* African-Americans | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Before MMA (2001-2005) | | | After MMA (2006-2010) | | | Diff of Diff over time† | DDD |
| | White | AA | Diff | White | AA | Diff | | |
| **Annual drug expenditures** | | | | | | | | |
| Part D | $3,452 | $3,300 | $152 | $4,002 | $3,728 | $274 | $122 | $446 |
| Comparison | $3,266 | $3,172 | $94 | $3,325 | $3,555 | -$230 | -$324 | |
| **Rx OOP spending** | | | | | | | | |
| Part D | $1,732 | $1,350 | $382 | $1,049 | $760 | $289 | -$93 | -$82 |
| Comparison | $1,162 | $978 | $184 | $931 | $758 | $173 | -$11 | |
| **Total number of Rx** | | | | | | | | |
| Part D | 48.7 | 50.5 | -1.8 | 51.4 | 51.9 | -0.5 | 1.3 | -4.2 |
| Comparison | 40.5 | 46.0 | -5.5 | 41.1 | 41.1 | 0.0 | 5.5 | |
| **Drug coverage** | | | | | | | | |
| Part D | 0.40 | 0.28 | 0.12 | 0.72 | 0.77 | -0.05 | -0.17 | -0.15*** |
| Comparison | 0.81 | 0.59 | 0.22 | 0.78 | 0.58 | 0.20 | -0.02 | |
| | **Whites *vs.* Hispanics** | | | | | | | |
| | White | Hispanic | Diff | White | Hispanic | Diff | Diff of Diff over time† | DDD |
| **Annual drug expenditures** | | | | | | | | |
| Part D | $3,452 | $2,668 | $784 | $4,002 | $3,469 | $533 | -$251 | -$397 |
| Comparison | $3,266 | $2,525 | $741 | $3,325 | $2,438 | $887 | $146 | |
| **Rx OOP spending** | | | | | | | | |
| Part D | $1,732 | $1,196 | $536 | $1,049 | $711 | $338 | -$198 | -$286 |
| Comparison | $1,162 | $1,030 | $132 | $931 | $711 | $220 | $88 | |
| **Total number of Rx** | | | | | | | | |
| Part D | 48.7 | 39.0 | 9.7 | 51.4 | 49.7 | 1.7 | -8.0 | -8.6** |
| Comparison | 40.5 | 35.1 | 5.4 | 41.1 | 35.1 | 6.0 | 0.6 | |
| **Drug coverage** | | | | | | | | |
| Part D | 0.40 | 0.19 | 0.21 | 0.77 | 0.86 | -0.09 | -0.30 | -0.25*** |
| Comparison | 0.81 | 0.50 | 0.31 | 0.78 | 0.52 | 0.26 | -0.05 | |

†Represents the difference of differences between White and minority before and after the MMA.

*p< 0.1. **p< 0.05. ***p< 0.01.

# Chapter 4: Closing the Medicare Doughnut Hole: The Early Impact of the Affordable Care Act on Prescription Drug Utilization and Out-of-Pocket Spending Among Medicare Beneficiaries with Part D Coverage

## Summary

The Affordable Care Act (ACA) includes provisions that reduce beneficiaries' cost sharing and eventually close the coverage gap (known as the "doughnut hole") that was originally part of Medicare prescription drug coverage implemented in 2006. The main objective of closing the coverage gap through the ACA is to reduce financial burden and increase affordability of prescription drugs for Medicare beneficiaries who obtain prescription drug coverage through Medicare Part D. This study examines the impact of the doughnut hole provisions of the ACA on overall prescription drug utilization and out-of-pocket (OOP) spending as well as by manufacturer type (brand vs. generic), through 2013 among Medicare Part D beneficiaries. The results indicate that overall OOP spending significantly decreased by an average of $119 per person without any significant impact on overall drug utilization. On the other hand, OOP spending on brand-name drugs and OOP spending as a share of total drug spending for Medicare seniors enrolled in Part D significantly dropped by an average of $100 and 2.7 percentage points, respectively, after closing the coverage gap. Also, the number of brand-name prescription drugs significantly decreased by 1.1 prescriptions. However, OOP spending on generic drugs and generic drug utilization did not significantly change.

When the sample population is limited to those who fell into the doughnut hole but did not reach the catastrophic coverage limit, overall OOP spending dropped significantly by an average of $179 per person, while overall drug utilization did not significantly change. OOP spending on brand-name drugs and OOP spending as a share of total drug spending were reduced by an average of $179 and 3.1 percentage points, respectively. Also, the number of brand-name prescription drugs and the number of brand-name prescription drugs as a share of total drug utilization significantly decreased by an average of 2.0 prescriptions and 5 percentage points, respectively. On the other hand, generic drug utilization significantly increased by an average of 5.1 prescriptions. The findings from this study suggest that overall OOP spending significantly decreased after closing the coverage gap, mainly because of a significant reduction in OOP spending on brand-name drugs. Conversely, the results show that the decrease in brand-name drug utilization is due to a shift from brand-name drugs to generics. As expected, the effects were considerably larger for people who reached the doughnut hole spending limits. The effects on drug spending are likely to increase in the future as more of the provisions are phased in.

## Introduction

Medicare Part D was enacted under the Medicare Modernization Act of 2003 to reduce costs, increase efficiency, and increase access to prescription medications for seniors and disabled persons.[81-83,95,96] However, a unique feature of Part D prescription drug coverage is the so-called "doughnut hole," which can substantially increase OOP costs for beneficiaries, especially those with high prescription drug use.[81-83] Under the 2010 standard benefit, Medicare beneficiaries with a Part D drug coverage plan had a $310 deductible and 25 percent copay per prescription until they reached the $2,830 coverage gap limit. Then, beneficiaries had to pay 100 percent of all drug costs until they incurred $6,440 in total drug costs.[145] This coverage gap is known as the doughnut hole.

Prior research has shown that one-fourth of Medicare beneficiaries reach the doughnut hole, and 20 percent of enrollees who reach the coverage gap either stop taking medications or reduce their medication use.[76,79,83,102] The likelihood of falling into the doughnut hole is higher among beneficiaries who have a significant need for prescription drugs, especially those with chronic conditions.[84,85] Evidence shows that higher treatment costs and cost sharing are associated with a lower rate of drug treatment, worse health outcomes, and low medication adherence.[146-151]

To alleviate expenses associated with the coverage gap and to make prescription drugs more affordable for Medicare beneficiaries, the ACA gradually reduces cost sharing from 100 percent in 2010 to 25 percent by 2020 for Part D beneficiaries who fall into the doughnut hole.[152] Starting in 2011, as depicted in Table 1, pharmaceutical firms are required to give a 50

percent discount for brand-name drugs and insurers are required to bear 7 percent of generic drug costs when beneficiaries fall into the doughnut hole, increasing to 75 percent for generic drugs by 2020.[152] For brand-name drugs, starting in 2013, insurers are required to bear 2.5 percent of drug costs when beneficiaries fall into the doughnut hole, increasing to 25 percent by 2020.[152]

A reduction in cost sharing or any price discounts could reduce the overall financial burdens that beneficiaries can face when they fall into the doughnut hole. The reduction in generic-drug cost sharing for Part D enrollees who reach the doughnut hole is gradual and may not be felt for some time, but any effects of price discounts on beneficiary spending for brand-name drugs may be more immediate, given the size of the discounts (50 percent). Therefore, this study examines the early effects of the ACA on overall prescription drug utilization and OOP spending as well as by manufacturer type (brand vs. generic), for Medicare Part D beneficiaries through 2013 as a result of the price discount and a reduction in cost sharing. To my knowledge, this study is the first to examine whether the provisions of the ACA that close the coverage gap have affected prescription drug utilization and OOP spending among Medicare seniors with Part D coverage. The study uses nationally representative survey data to examine changes after 2011 in overall OOP spending, total prescription drug use, OOP on brand-name and generic prescription drugs, and the total number of brand-name and generic prescriptions filled during the year.

## Literature Review

This section discusses prior research that has studied the impact of the Medicare doughnut hole on prescription drugs. It includes a review of literature that studied the impact of Medicare Part D and Medicare doughnut hole on prescription drug utilization, spending, and adherence. The focus is on these areas because the goal of Part D was to give seniors better access to prescription drugs and to reduce the associated financial burdens.

### Drug Utilization

Several studies have been conducted since the inception of Medicare Part D to examine the impact of Medicare Part D and the Medicare doughnut hole on drug utilization. Existing literature demonstrates that the introduction of Medicare Part D was associated with an increase in drug utilization. Although the studies used different databases and various time frames, the results are consistent: prescription drug utilization increased by 5 to 32 percent among Medicare beneficiaries.[116-122] However, almost all of the studies that looked at the impact of the Medicare doughnut hole on drug utilization found that the presence of a doughnut hole negatively affected the prescription fulfillment decisions made by Part D beneficiaries. The effects were in the form of delaying medications, switching medications, stopping at least one medication, or both delaying and stopping medications.[153-157] A study by Zhang et al. found that prescription drug use decreased by 14 percent for Medicare beneficiaries who entered the doughnut hole relative to their use before entering the doughnut hole.[158]

**Drug Expenditures**

Although existing literature extensively examined the impact of Part D on prescription drug expenditures, only a few studies have examined the effect of the Medicare doughnut hole on prescription drug expenditures.

Existing literature shows that OOP spending significantly decreased after Part D implementation and the degree of this reduction ranged from 18 to 49 percent.[118-122] However, using the Medicare Current Beneficiary Survey data, Patel et al. found that the presence of the Medicare doughnut hole substantially increased total and OOP annual expenditures for Medicare beneficiaries who had End-Stage Renal Disease (ESRD).[154] This demonstrates that prescription drug expenditures will increase as people with chronic diseases, such as ESRD fall into the doughnut hole. Also, literature has shown that the Medicare coverage gap resulted in lower total drug costs, but higher OOP spending among Medicare beneficiaries with diabetes. Although a reduction in total drug costs may seem unusual, the reduction in total costs appears to be due to a low adherence to medications among those who faced the coverage gap.[159] Low adherence to prescription drugs can result in lower total drug costs, especially among diabetic patients because diabetes can be controlled with appropriate diets and exercises.

**Drug Adherence**

Since the inception of Part D, several studies have estimated the impact of Part D and the Medicare doughnut hole on drug adherence. The prior literature demonstrates that the existence of the Medicare doughnut hole has a negative impact on prescription drug adherence. Studies show that despite increases in drug access due to Medicare Part D, the

presence of the coverage gap could potentially reduce drug adherence, especially among those who fall into the doughnut hole.

Using claims data, Gu et al. found that the Medicare doughnut hole has a significant negative impact on medication adherence among beneficiaries with diabetes.[160] Another study that used survey data found that Medicare beneficiaries who take insulin are at higher risk of cost-related non-adherence compared to Medicare beneficiaries who have drug gap coverage.[161] Also, prior research has shown that eliminating the coverage gap would not affect adherence to generic drugs but could reduce cost-related non-adherence for brand-name oral antidiabetic medications.[162]

Existing literature primarily focuses on antidiabetic medications. However, in this analysis I include all types of medications without limiting to any therapeutic class. Such limits may affect the results because beneficiaries with different conditions may have different behavior patterns.

**Literature Gap**

Although most research to date has examined how the introduction of Part D affected prescription drug use and expenditures, only a few studies have examined the impact of the coverage gap on prescription drug use and expenditures. Overall, the literature indicates that the Medicare doughnut hole had a negative impact on prescription drug use and increased OOP spending for Medicare beneficiaries. However, the existing literature does not examine the impact of closing the doughnut hole on prescription drug utilization and expenditures. In addition, no study has stratified the effect by manufacturer type (brand or generic). This is

important because it can reveal the extent to which the reduction in generic drug cost sharing and brand-name drug discounts can impact beneficiaries' behavior. By conducting this study, I will quantify the impact of closing the Medicare doughnut hole on prescription drug use and OOP spending.

**Aims and Hypotheses**

Prescription drug costs play an important role in increasing financial burdens. Although Medicare Part D was intended to reduce costs and increase access to prescription medications, the existence of the doughnut hole can substantially affect OOP spending and access to prescription drugs for beneficiaries, especially those with high prescription drug use.

This study examines the early effects of the ACA on overall prescription drug utilization and OOP spending for Medicare Part D beneficiaries through 2013 as a result of the price discount and a reduction in cost sharing and stratifies the effect by manufacturer type (brand vs. generic). The study will determine whether prescription drug use and OOP spending have changed after the closing of the Medicare doughnut hole began in 2011 and how changes differ by manufacturer type. The specific aim is as follows:

1. Examine changes in prescription drug use and OOP spending after the ACA doughnut hole provisions began to phase in.

H1: Overall OOP spending will decrease following the doughnut hole closing because beneficiaries will receive help when they fall into the doughnut hole. The effect will

be significant for brand-name drugs, given the size of the discounts (50 percent) compared to generic drugs.

H2: The number of prescription drugs will increase following the doughnut hole closing because it will save more money for beneficiaries to spend on drugs when they fall into the doughnut hole. The effect will be significant for brand-name drugs, given the size of the discounts (50 percent) compared to generic drugs.

**Conceptual Framework and Economic Theory**

Healthcare possesses uncertainties due to disease unpredictability and expensive health care services, including but not limited to prescription drugs, hospital care, and physician visits. Health insurance—including Medicare Part D coverage—increases access to care and reduces uncertainty for risk-averse individuals by assuring financial assistance in times of need. However, most insurance coverage plans require cost sharing. The purpose of cost sharing is to make individuals more conscious of health care costs and reduce unnecessary health care utilization.[130]

Because individual factors, health service system factors, and social factors are the main characteristics that can enhance or impede health care utilization, I adopted the Andersen model[131] to measure the impact of closing the coverage gap on prescription drug use and expenditures. According to the Andersen model, health care consumption is determined by three elements: predisposing factors, enabling factors, and need. I include age and gender as predisposing factors because the risks of developing chronic diseases and healthcare utilization are associated with age, gender, activity level, and eating habits.[135,136] In general, older people

have more tendencies toward using medications because they have comorbid conditions, and their health deteriorates faster over time. I also include race and education as social structures under predisposing factors because minorities have higher chronic disease prevalence and higher rates of disease complications, such as renal disease, blindness, and amputations.[107-109,137] Moreover, education plays a significant role in controlling chronic disease complications.[138,139] In addition to health insurance coverage for prescription drugs, I include social and economic resources such as income as an enabling factor because they facilitate the use of services. Need refers to the presence or severity of illness, and I identify the number of chronic conditions for each individual to reflect the severity of a disease.

Overall, people who are eligible for Part D will be more inclined to use health care, because as an enabling factor it allows individuals to fill their prescriptions and reduces their OOP spending. Disease severity and the number of chronic conditions fall into the category of need.

## Methods

### Data

This analysis is based on data from the 2008–2013 Medical Expenditure Panel Survey (MEPS), conducted by the Agency for Healthcare Research and Quality. MEPS includes

nationally representative samples of the noninstitutionalized[§§§] population of the United States and collects detailed information on health care expenditures and use of services, insurance coverage, sources of payment, health status, employment, and other sociodemographic characteristics. I chose MEPS over other databases such as the Medicare Current Beneficiary Survey (MCBS) for several reasons. First, MEPS data are more recent and easier to obtain; the latest MCBS publicly available data are for the year 2012. Second, MEPS collects data from a sample of respondents' providers to verify use of services, charges, and sources of payments. Unlike MCBS, which does not collect information from pharmacies, MEPS verifies collected information from respondents about each of the prescriptions they received during the year and the sources of payment by following up with the pharmacies used by survey respondents.[163] Third, MEPS is less likely than MCBS to have differential underreporting of utilization in the HMO and fee-for-service sectors of Medicare because it does not rely extensively on insurance statements and Explanation of Medicare Benefits forms to collect utilization data from survey respondents. Finally, MEPS includes more accurate information on non-Medicare spending and beneficiaries who are not elderly, which expands the size of the comparison group.

In this study, I used the full-year consolidated data under the Household Component files, which include information on health status, demographic and socioeconomic

[§§§] The civilian noninstitutional population consists of people 16 years of age and older residing in the 50 states and the District of Columbia who are not inmates of institutions (prisons, mental facilities, long-term-care facilities, etc.).

characteristics, employment, access to care, and satisfaction with health care.[140] This was supplemented with data from the Medical Conditions and Prescribed Medicines files, which provide specific information about individuals' medical conditions and their prescriptions, including their insurance status, total expenditures, source of payment (including OOP spending), and time of diagnosis.

The sample for this analysis included all individuals 55 years of age and older. The overall sample included a total of 17,037 MEPS respondents; 4,215 of them were 65 years of age and older and enrolled in Medicare Part D (the Part D group), and 12,822 of whom were 55 years of age and older and had private prescription drug coverage (the comparison group). The comparison group included 3,002 participants who were 65 years of age and older and had only private prescription drug coverage. I excluded all individuals with family incomes below 150 percent of the FPL because they were eligible for the low-income subsidy. The low-income subsidy program, which was established through Part D, provides assistance to Medicare beneficiaries with limited income and assets. These include Part D premiums, deductibles, copayments, and costs associated with the coverage gap.[164] Thus, they were not affected by the policy change through the ACA because they paid little or no cost sharing in the doughnut hole prior to the policy change.[165,166]

**Variables**

During each round of MEPS, respondents were asked about the type of health insurance coverage they were enrolled in, such as Medicare, Medicaid, or a private insurance plan. They were also asked whether they had Medicare prescription drug benefit coverage, also known as

Part D. Furthermore, those who had at least one prescription medication purchase were asked whether the respondent had a usual third-party payer for prescription medications, and if so, what type of payer. Persons were classified as being enrolled in Medicare Part D coverage if they responded affirmatively to a question asking whether they were covered by Medicare and covered by the prescription drug benefit.

During each round of MEPS, respondents were asked about the name of each prescription filled, the total and OOP cost of each prescription, and a list of the names, addresses, and types of pharmacies that filled the household's prescriptions. With each participant's consent, MEPS contacted the pharmacy to get detailed information on date filled, national drug code, medication name, strength (amount and unit), quantity (package size and amount dispensed), and payments by source. If consent was not granted, a participant's own self-reported information was used. Because I intended to stratify the effect of closing the coverage gap on drug utilization and OOP spending by brand versus generic, and MEPS does not include any information regarding manufacturer type (brand vs. generic), I used Red Book,[****] (available through Micromedex at the University of Maryland in Baltimore) and the Food and Drug Administration[††††] website to obtain drug manufacturer type. Summing across all three rounds in the MEPS during the calendar year, I calculated OOP spending on brand-name and

[****]http://www.redbook.com/redbook/online/

[††††] https://www.accessdata.fda.gov/scripts/cder/drugsatfda/

generic drugs. I also calculated the number of brand-name and generic prescription drugs filled for each individual by counting the associated number of prescriptions (including refills).

**Analytical Methods**

The basic approach is to (a) examine changes in prescription drug utilization and spending before and after the implementation of the doughnut hole provisions of the ACA for Part D beneficiaries; and (b) compare these changes to other Medicare and near-elderly adults to determine whether the changes were due to the ACA or other factors. I adopted a difference-in-differences (DD) methodology to estimate the impact of closing the coverage gap on drug utilization and OOP spending.

The model compared differences in outcomes between Medicare beneficiaries aged 65 years and older who had Medicare Part D coverage but had no Medicaid or private prescription drug coverage (the Part D group) with Medicare beneficiaries aged 65 years and older and adults aged 55–64 (near-elderly) who did not have prescription drug coverage through Medicare or Medicaid, but had private prescription drug coverage (the comparison group) before and after 2011. I did not restrict the comparison group to seniors because limiting the sample population to those with spending equal to the doughnut hole would leave no observation for some years. The comparison group represents the individuals who are most similar to Medicare Part D beneficiaries in terms of their sociodemographic and health characteristics as well as their prescription drug utilization and coverage but are not affected by the closing or the existence of the doughnut hole.

The methodology assesses the impact of the ACA by comparing changes in utilization and OOP spending for Part D beneficiaries before and after 2011 to changes for the comparison group. DD analysis is acceptable if both the Part D and the comparison groups would have experienced similar trends in drug use and expenditures in the absence of the doughnut hole provisions of the ACA. Before estimating the models, I formally tested for trend similarities in the outcome variables during the years leading up to the doughnut hole closure. I compared unadjusted differences between the Part D and comparison groups for aforementioned measures from 2008 to 2010. As estimates show in Table 2, there is no significant difference in OOP spending and number of prescribed medicines for both brand-name and generic drugs. The regression-based DD methodology further controls for other differences between the Part D and comparison groups that may affect utilization and spending, including age, gender, race/ethnicity, income, perceived health status, and the number of chronic conditions (based on MEPS priority conditions, which include some of the most prevalent and highest cost conditions[‡‡‡‡]). The analysis controlled for changes in the characteristics of both the Part D and the comparison groups over time that might also affect their utilization and spending.

The equation below represents the basic structure of the DD model that I used to estimate the impact of closing the coverage gap on drug use and OOP spending.

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[‡‡‡‡] These include high blood pressure, coronary heart disease, angina, myocardial infarction, stroke, emphysema, chronic bronchitis, high cholesterol, cancer, diabetes, arthritis, asthma, and attention deficit hyperactivity disorder.

$$Y_{it} = \beta_0 + \beta_1 \text{Time}_i + \beta_2 \text{Treatment}_{it} + \beta_3 (\text{Treatment*Time})_{it} + Z_i + \varepsilon_{it}$$

In this model, *i* represents an individual and *t* represents year. *Y* denotes outcome measures, which are the total number of prescriptions filled during the year, overall OOP spending on prescription drugs, the total number of brand-name or generic prescriptions filled during the year, OOP spending on brand-name or generic drugs, number of brand-name prescription drugs as a share of total drug utilization, or OOP spending as a share of total drug spending. *Time* is a binary vector of time when the Medicare Part D coverage gap began to decrease following implementation of the ACA. It is 1 if individuals were surveyed in 2011 or after; otherwise it is 0. I excluded individuals who were 64 at the beginning of the year to prevent double counting. *Treatment* is a dummy variable representing the Part D and the comparison groups. It is 1 if they were Medicare beneficiaries aged 65 years and older who had Medicare drug benefit but had no Medicaid or private prescription drug coverage (the Part D group); otherwise it is zero (the comparison group). There is an interaction term between being in the treatment group and the time the survey was conducted, which is the estimate of interest, $\beta_3$. The estimate of this variable shows the extent to which closing the coverage gap has impacted drug use and OOP spending between the Part D and the comparison groups. A positive coefficient means that closing the coverage gap increased drug utilization and spending, while a negative coefficient means the opposite. *Z* is a vector of all other covariates that could affect outcomes, including education, race, health status, sex, the number of chronic conditions, and marital status.

To construct the chronic condition index, I added all priority conditions reported in MEPS, including high blood pressure, coronary heart disease, angina, myocardial infarction, stroke, emphysema, chronic bronchitis, high cholesterol, cancer, diabetes, arthritis, and asthma. I included these conditions because they are prevalent among senior and near-elder populations and the existence of them can affect prescription drug use and expenditures. I excluded attention deficit hyperactivity disorder because it is not relevant for the Medicare population, and there were no persons with this condition in the sample for this analysis. Then, I categorized them in four categories: (a) no chronic conditions, (b) one chronic condition, (c) two chronic conditions, and (d) three or more chronic conditions. Although mental health diseases are common among the near-elderly and seniors, it is not included as one of the priority conditions in MEPS. However, MEPS collects information on perceived mental health status. Therefore, perceived mental health status was separately used to control for possible psychological disorders.

Serial correlation is one of the biggest problems in the DD method that can undermine the validity of estimates.[143] I aggregated the data into two groups: pre- and post-interventions. Creating two intervention groups reduces the likelihood of serial correlation between observations. To measure the impact of Part D on prescription drug utilization, I applied a generalized linear model (GLM) because some observations had zero prescription drugs and the distribution of prescription drugs was heavily skewed to the right. Using GLM allows accounting for a response variable that has a nonstandard distribution and correctly measures the number of prescriptions without assuming that the drug utilization values are normally distributed. I chose a GLM with a log link and gamma distribution for OOP spending and a GLM with a log link

and negative binomial distribution for the number of prescription drugs. I chose a GLM with a log link and gamma distribution because expenditures are continuous but nonnormal. For utilization, I chose a GLM with a log link and negative binomial distribution rather than Poisson distribution because Poisson distribution assumes that the mean and variance are the same, whereas the dataset showed that variances of outcomes were greater than the means.

To measure the impact of closing the coverage gap on OOP spending as a share of total drug spending and brand-name prescription drugs as a share of total drug utilization, an ordinary least squares model was applied.

To measure the impact of closing the coverage gap on drug utilization and OOP spending, I examined three different scenarios. In the first scenario, I examined changes in utilization and OOP spending for all Part D beneficiaries, regardless of the level of prescription drug utilization and spending. In the second scenario, I examined changes specifically for those beneficiaries who reached the Part D doughnut hole coverage limits. I did this by restricting the sample size to the Part D and comparison groups who spent more than the initial coverage limit for each year, including $2,510 or more in 2008, $2,700 or more in 2009, $2,830 or more in 2010, $2,840 or more in 2011, $2,930 or more in 2012, and $2,970 in 2013. In the third scenario, I examined changes for those beneficiaries who reached the Part D doughnut hole coverage limits but did not reach the catastrophic threshold. Beneficiaries are responsible for only 5 percent of prescription drug costs after reaching the catastrophic threshold, which can affect their drug use and expenditures. Therefore, limiting the sample population to those who fell into the doughnut hole but did not reach the catastrophic coverage allowed me to

accurately estimate the impact of closing the doughnut hole on prescription drug use and expenditures. I did this by restricting the sample size to both the Part D and the comparison groups who spent more than the initial coverage limit but less than the catastrophic coverage limit for each year ($2,510 to $5,727 in 2008; $2,700 to $6,154 in 2009; $2,830 to $6,441 in 2010; $2,840 to $6,448 in 2011; $2,930 to $6,658 in 2012; and $2,970 to $6,734 in 2013).

All OOP spending was converted to inflation-adjusted 2013 dollars using the all-items Consumer Price Index (CPI). I used CPI all-items instead of CPI-drugs because the former represents all goods and services purchased for consumption, including prescription drugs. Although CPI all-items does not reflect price inflation specific to drugs, the inability of CPI-drugs to properly adjust for quality and entry of new drugs reduces its precision. Therefore, I used the CPI all-items adjustment to have a better and more generalizable price representative.[144]

I used sampling weights, strata, and primary sampling unit provided in MEPS to account for differential selection probabilities, to adjust for nonresponses, to control for design effects, and to generate appropriate standard errors to reflect a nationally representative sample of the noninstitutionalized civilian U.S. population. Stata 12 was used to conduct all statistical analyses (StataCorp, College Station, TX).

## Results

### Study Population Characteristics

Medicare Part D beneficiaries differ from the comparison group in a number of characteristics. About 17,000 persons were included in this analysis. Among Part D

beneficiaries, about 23 percent had less than a high school education compared to 11 percent for the comparison group (Table 3). Part D beneficiaries are also more likely to be low income—150% FPL<*x*<200% FPL (17 percent) compared to 6 percent in the comparison group. As previously mentioned, all individuals with family incomes below 150 percent of the federal poverty level (FPL) were excluded because they were eligible for the low-income subsidy. Part D beneficiaries were also more likely to be in fair or poor health (about 19 percent) compared to about 13 percent for the comparison group. Moreover, Part D beneficiaries were more likely to have three or more chronic conditions (65 percent) compared to 43 percent for the comparison group.

**Unadjusted Estimates of Prescription Drug Spending and Utilization**

Table 4 shows the simple means for overall OOP spending on prescription drugs and the total number of drugs. It also represents OOP spending and drug use by manufacturer type (brand vs. generic). These are unadjusted estimates for each group before and after the ACA. The results show that overall OOP spending significantly decreased among Part D beneficiaries—from $694 before the ACA to $493 after the implementation of the doughnut hole provisions. Also, there were significant increases in the total number of prescription drugs for both the Part D and the comparison groups.

The results show that OOP spending on brand-name drugs significantly decreased among Part D beneficiaries—from $468 before the ACA to $268 after the implementation of the doughnut hole provisions. Also, OOP spending significantly decreased for the comparison group. There were significant reductions in the total number of brand-name prescription drugs

for both the Part D and the comparison groups after the implementation of the doughnut hole provisions. Although the results show that OOP spending on generic drugs did not change significantly, there were significant increases in the total number of generic prescription drugs for the Part D group after the implementation of the doughnut hole provisions.

Among Part D beneficiaries who reached the coverage gap, there was a significant decrease in total drug use only among the comparison group. When the effect was stratified by manufacturer type, there were significant reductions in OOP spending and the total number of brand-name prescription drugs for both the Part D and the comparison groups after the implementation of the doughnut hole provisions. Presumably, the reduction in brand-name drug use happened because beneficiaries were substituting generics for brand-name drugs. On the other hand, the results show that the number of generic drugs significantly increased among both the Part D and the comparison groups.

Among Part D beneficiaries who reached the coverage gap but did not reach the catastrophic threshold, overall OOP spending significantly decreased among both groups. When the effect was stratified by manufacturer type, the results show that OOP spending on brand-name drugs and the total number of brand-name drugs significantly decreased among the Part D and the comparison groups. On the other hand, the results show that only the number of generic drugs significantly increased in both the Part D and the comparison groups.

**Impact of the ACA Doughnut Hole Provisions**

Table 5 shows the results of the DD analysis. The results reflect adjusted estimates of overall OOP spending and utilization and the stratified OOP spending and utilization by

manufacturer type (brand vs. generic), after controlling for differences between Part D beneficiaries and the comparison groups in demographic and socioeconomic characteristics, as well as health status and the number of chronic conditions. In other words, these are adjusted predictions for $B_3$ in the model and have been calculated for both the treatment and the comparison groups before and after the ACA. The difference reflects the net change in utilization and OOP spending in the Part D group relative to the comparison group.

The results show that overall OOP spending decreased by $119 for the Part D group after implementation of the ACA doughnut hole provisions. When I restricted the sample size to beneficiaries who spent more than the initial coverage limit, the overall OOP spending decreased by $179, although the difference was not statistically significant. OOP spending significantly decreased by $171 after restricting the sample size to those who spent more than the initial coverage limit but did not reach the catastrophic threshold.

The results show that total drug utilization did not change following implementation of the ACA doughnut hole provisions. However, the overall prescription drug use significantly increased by an average of six prescriptions among beneficiaries who spent up to the coverage limit. When I restricted the sample size to those who reached the doughnut hole coverage gap but did not reach the catastrophic threshold, the overall prescription drug use increased by an average of 2.8 prescriptions, although the difference was not statistically significant.

**Brand**

The results show that OOP spending decreased by $100 for the Part D group after implementation of the ACA doughnut hole provisions. When I restricted the sample size to

beneficiaries who spent more than the initial coverage limit, the OOP spending on brand-name drugs decreased by $156 after closing the coverage gap, although the difference was not statistically significant. However, OOP spending on brand-name drugs significantly decreased by $179 after restricting the sample size to those who spent more than the initial coverage limit but did not reach the catastrophic threshold.

The results also show that OOP spending on brand-name drugs, as a share of overall drug expenditures (both brand and generic drugs), significantly decreased by 2.7 percentage points for the Part D group after implementation of the ACA doughnut hole provisions. When I restricted the sample size to beneficiaries who spent more than the initial coverage limit, OOP spending on brand-name drugs, as a share of overall drug expenditures (both brand and generic drugs), significantly decreased by 3.7 percentage points after closing the coverage gap. In addition, when I restricted the sample size to those who spent more than the initial coverage limit but did not reach the catastrophic threshold, OOP spending on brand-name drugs, as a share of overall drug expenditures (both brand and generic drugs), significantly decreased by 3.1 percentage points.

Furthermore, the results show that total brand-name prescription drug utilization decreased following implementation of the ACA doughnut hole provisions. The number of brand-name prescription drugs significantly decreased by an average of 1.1 prescriptions among beneficiaries who spent up to the coverage limit. When I restricted the sample size to those who reached the doughnut hole coverage gap but did not reach the catastrophic threshold, the number of brand-name prescription drugs significantly decreased by an average

of 2.0 prescriptions. The number of brand-name prescription drugs as a share of total drug utilization decreased more than 4 percentage points among those who reached the doughnut hole coverage gap.

**Generic**

Finally, Table 5 also reflects adjusted estimates of utilization and OOP spending on generic drugs after controlling for differences between Part D beneficiaries and the comparison groups in demographic and socioeconomic characteristics, as well as health status and the number of chronic conditions. The results show that total generic drug utilization increased following implementation of the ACA doughnut hole provisions, especially among those who spent more than the initial coverage limit. The results demonstrate that Medicare beneficiaries are substituting generics for brand-name drugs as plans' cost sharing for generic drugs increases over time.

## Discussion

The findings of this study demonstrate that despite an increase in overall drug utilization, overall OOP spending decreased significantly after closing the coverage gap. The effect becomes larger when the sample size is restricted to those who fell into the doughnut hole. The reduction in OOP spending and the increase in utilization likely reflect the price discount and a reduction in cost sharing.

When the effect was stratified by brand versus generic, the results show that utilization and OOP spending on brand-name drugs decreased significantly after closing the coverage gap,

and the effect was larger among Part D beneficiaries who reached the doughnut hole. The reduction in OOP spending on brand-name drugs likely reflects the 50 percent discount on the cost of brand-name drugs that pharmaceutical companies were required to give Part D enrollees who reached the doughnut hole in 2011, 2012, and 2013. However, other reasons such as patent expiration and generic substitution at pharmacies could result in this reduction.

The results indicate that OOP spending decreased after implementation of the ACA doughnut hole provisions. This is consistent with the intent of the doughnut hole provisions, which was to increase access to prescription drugs and reduce the economic burden associated with prescription drugs. Although an increase in the total number of brand-name prescription drugs was expected, given the size of the discount, the results show that the total number of brand-name prescription drugs decreased after closing the coverage gap. It is mostly because beneficiaries are substituting generics for brand-name drugs. Even though beneficiaries get a greater discount on brand-name drugs when they fall into the doughnut hole, there is a big difference in drug prices between a brand-name drug and its generic substitute. For example, in 2013, the wholesale acquisition cost for 30 pills of Actos 30 mg, an antidiabetes drug, was about $360, while it was $13 for Pioglitazone, its generic substitute. After taking the discount and cost sharing into account, 30 pills of Actos 30 mg could cost beneficiaries $170 when they were in the doughnut hole, while it was $10 for Pioglitazone. Therefore, it is likely that beneficiaries are substituting generics for brand-name drugs, especially when they fall into the doughnut hole.

A negative effect on brand-name drug utilization could also be due to other utilization behaviors that individuals might engage in order to reduce their costs, such as skipping medications on alternate days or splitting pills. Furthermore, a shift in prescription supply from 30-day to 90-day, which is common among individuals with chronic conditions, can justify this effect because their records would show one prescription instead of three prescriptions. However, the MEPS does not ask any questions regarding these behaviors or prescription supply.

To my knowledge, this is the first study to examine the impact of closing the coverage gap on prescription drug utilization and spending. There are, however, a number of limitations to the analysis.

First, because closing the coverage gap started in 2011 and gradually expands through 2020, the analysis shows only the early effects of the policy and not the full effects that are likely to grow in subsequent years. Despite a continued high cost-sharing rate for generic drugs in the 3 years following implementation, the discount for brand-name drugs is large enough (50 percent) to expect some immediate change in prescription drug spending, especially for those who reach the doughnut hole coverage gap.

Second, while the analysis controls for differences based on age, gender, race/ethnicity, income, the number of comorbid conditions, and health status, there may be other differences between Part D beneficiaries and the comparison groups not accounted for in the analysis that could affect the results. However, the combination of Medicare beneficiaries and near-elderly

adults with a private prescription drug plan is arguably the best available comparison group in the MEPS or any other data source that could be used to conduct this study.

Third, Medicare beneficiaries can receive their drug insurance coverage through stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. PDPs only cover drug expenditures, whereas MA-PDs cover all Medicare benefits including drugs. These two different plans could have different impacts on beneficiaries' OOP spending, as beneficiaries with MA-PD plans will face less financial burden compared to beneficiaries with PDP plans. Unfortunately, I was not able to differentiate the impact using the MEPS data.

The impact of the ACA on Medicare Part D prescription drug spending is likely to increase as additional provisions phase in. Although discounts for brand-name drugs will stay the same (50 percent) through 2020, patient cost sharing for brand-name drugs will decrease to 45 percent in 2015 and 25 percent in 2020, while cost sharing for generic drugs will decrease to 65 percent in 2015 and 25 percent in 2020. The gradual closing of the coverage gap comes at a time of accelerating growth of specialty drugs in the pipeline, mostly higher cost biological drugs, which are expected to increase overall healthcare costs in future.

In sum, the findings from this study suggest that the ACA doughnut hole provisions appear to be effective by decreasing OOP spending and increasing access to prescription drugs for Part D beneficiaries. As expected, the effects are considerably larger for people who reach the doughnut hole spending limits. The effects on drug spending are likely to increase in the future as more of the provisions are phased in.

Table 1: Cost Sharing and Pharmaceutical Discounts for Part D Beneficiaries Who Fall Into the Doughnut Hole by Drug Type, Brand-Name vs. Generic

| Plan year | Generic drugs | | Brand-name drugs | | |
|---|---|---|---|---|---|
| | % Medicare recipient pays | % Plan pays | % Medicare recipient pays | % Plan pays | % Manufacturer pays |
| <2011 | 100% | 0% | 100% | 0% | 0% |
| 2011 | 93% | 7% | 50% | 0% | 50% |
| 2012 | 86% | 14% | 50% | 0% | 50% |
| 2013 | 79% | 21% | 47.5% | 2.5% | 50% |
| 2014 | 72% | 28% | 47.5% | 2.5% | 50% |
| 2015 | 65% | 35% | 45% | 5% | 50% |
| 2016 | 58% | 42% | 45% | 5% | 50% |
| 2017 | 51% | 49% | 40% | 10% | 50% |
| 2018 | 44% | 56% | 35% | 15% | 50% |
| 2019 | 37% | 63% | 30% | 20% | 50% |
| 2020 | 25% | 75% | 25% | 25% | 50% |

Table 2: Trends in the Unadjusted Differences Between the Part D and the Comparison Groups Before the ACA

| Outcome measures | Difference in Part D group, 2008-2010 | Difference in comparison group, 2008-2010 | DD‡ | t(p-value) |
|---|---|---|---|---|
| **Overall** | | | | |
| Rx OOP spending | -$2.6 | -$19.8 | $17.2 | 0.80 (0.06) |
| Total number of Rx | -1.2 | -0.3 | -0.9 | 0.68 (0.17) |
| **Brand-name drugs** | | | | |
| Rx OOP spending | -$1.6 | -$30.0 | $28.4 | 0.26 (0.61) |
| Total number of Rx | -2.8 | -2.2 | -0.6 | 0.35 (0.55) |
| **Generics drugs** | | | | |
| Rx OOP spending | -$1.0 | $9.2 | -$10.2 | 0.68 (0.17) |
| Total number of Rx | 1.6 | 1.9 | -0.3 | 0.83 (0.04) |

‡Represents the difference between the Part D and comparison groups.

Table 3. Percentage Distribution of Demographic Characteristics of the Medical Expenditure Panel Survey Sample by Target Group

| Characteristics | All respondents (N=17,037) % | | Those with spending equal to doughnut hole (N=3,571) % | |
|---|---|---|---|---|
| | Part D N=4,215 | Comparison N=12,822 (3,002 are seniors) | Part D N=981 | Comparison N=2,590 |
| **Education** | | | | |
| Less than high school | 23.6*** | 10.9 | 24.9*** | 11.7 |
| High school graduate | 32.2*** | 25.6 | 33.1*** | 26.5 |
| Some college or more | 44.2*** | 63.5 | 42.0*** | 61.8 |
| **Sex** | | | | |
| Male | 43.6*** | 48.4 | 42.9** | 48.7 |
| Female | 56.4*** | 51.6 | 57.1** | 51.3 |
| **Poverty level** | | | | |
| Low income (150% FPL<x<200% FPL) | 16.8*** | 6.2 | 16.5*** | 6.4 |
| Middle income (200% FPL<x<400% FPL) | 41.3*** | 27.6 | 42.9*** | 28.4 |
| High income (400% FPL<x) | 41.9*** | 66.2 | 40.6*** | 65.2 |
| **Race/Ethnicity** | | | | |
| Non-Hispanic White | 84.4* | 82.6 | 86.1 | 85.9 |
| Non-Hispanic Black | 5.8*** | 7.4 | 5.3 | 6.6 |
| Hispanic | 6.7*** | 5.2 | 5.1 | 4.2 |
| Non-Hispanic Other | 3.1*** | 4.8 | 3.5 | 3.3 |
| **Health status** | | | | |
| Excellent & Very Good | 48.5*** | 57.0 | 29.6*** | 36.5 |
| Good | 32.6* | 30.2 | 38.8 | 37.3 |
| Fair | 14.7*** | 10.1 | 22.6 | 19.3 |
| Poor | 4.2*** | 2.7 | 9.0* | 6.9 |
| **Marital status** | | | | |
| Married | 58.1*** | 72.6 | 57.8*** | 72.6 |
| Not married | 42.9*** | 27.3 | 42.2*** | 27.4 |
| **Chronic Conditions** | | | | |
| 0 | 2.7*** | 9.1 | 0.7** | 2.2 |
| 1 | 11.1*** | 21.5 | 4.8*** | 10.5 |
| 2 | 21.4*** | 26.0 | 9.9*** | 16.9 |
| ≥3 | 64.8*** | 43.4 | 84.6*** | 70.4 |

*Sources:* Author's analysis of data from the Medical Expenditure Panel Surveys, Household Component, 2008–13.

*Notes:* Part D group is adults aged 65 years and older who had Medicare drug benefit but had no Medicaid coverage or private prescription drug coverage. The comparison group is Medicare beneficiaries aged 65 years and older and adults aged 55–64 years who had no Medicare drug benefit and Medicaid coverage but had private prescription drug coverage.

*Difference is statistically significant at 0.1 level. **Difference is statistically significant at 0.05 level.
***Difference is statistically significant at 0.01 level.

Table 4. Unadjusted Estimates of Effects of Closing the Doughnut Hole on Drug Use and Expenditures.

| Outcomes | All respondents (N=17,037) | | | | Those with spending equal to doughnut hole (N=3,571) | | | | Those with spending equal to doughnut hole but less than the catastrophic coverage (N=2,496) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Part D | | Comparison | | Part D | | Comparison | | Part D | | Comparison | |
| | Before ACA | After ACA | Before ACA | After ACA | Before ACA | After ACA | Before ACA | After ACA | Before ACA | After ACA | Before ACA | After ACA |
| **Overall** | | | | | | | | | | | | |
| OOP Spending | $694 | $493*** | $507 | $423*** | $1,606 | $1,325 | $1,261 | $1,183 | $1,310 | $1,069*** | $967 | $868** |
| Number of Rx | 31.9 | 29.5** | 22.9 | 21.1*** | 56.8 | 61.9 | 47.8 | 45.1*** | 50.2 | 51.3 | 40.3 | 38.2 |
| **Brand** | | | | | | | | | | | | |
| OOP Spending | $468 | $268*** | $338 | $243*** | $1,197 | $887*** | $920 | $811* | $952 | $674*** | $681 | $566*** |
| Number of Rx | 9.5 | 5.2*** | 8.3 | 5.2*** | 21.8 | 15.3*** | 21.0 | 15.8*** | 18.3 | 11.6*** | 17.1 | 12.5*** |
| **Generic** | | | | | | | | | | | | |
| OOP Spending | $226 | $226 | $169 | $180 | $407 | $438 | $341 | $372 | $358 | $395 | $286 | $302 |
| Number of Rx | 22.4 | 24.3* | 14.5 | 15.9*** | 35.0 | 46.5*** | 26.7 | 29.3* | 31.9 | 39.7*** | 23.2 | 25.7* |

*Sources:* Author's analysis of data from the Medical Expenditure Panel Surveys, Household Component, 2008–13.
*Notes:* Part D group is adults aged 65 years and older who had Medicare drug benefit but had no Medicaid coverage or private prescription drug coverage. The comparison group is Medicare beneficiaries aged 65 years and older and adults aged 55–64 years who had no Medicare drug benefit and Medicaid coverage but had private prescription drug coverage. OOP = out-of-pocket. Rx = prescription drugs. $ = expenditures. % = percent.
**Difference is statistically significant at 0.05 level. ***Difference is statistically significant at 0.01 level.

Table 5. Difference-in-Differences Estimates of Effects of Closing the Doughnut Hole on Drug Use and Expenditures.

| Outcome | All respondents (N=17,037) | | | | | Those with spending equal to doughnut hole (N=3,571) | | | | | Those with spending equal to doughnut hole but less than the catastrophic coverage (N=2,496) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Part D | | Comparison D | | Diff | Part D | | Comparison D | | Diff | Part D | | Comparison D | | Diff |
| | Before | After | Before | After | | Before | After | Before | After | | Before | After | Before | After | |
| **Overall** | | | | | | | | | | | | | | | |
| OOP spending | $416 | $488 | $508 | $699 | **-$119*****| $1,019 | $1,210 | $1,126 | $1,496 | **-$179** | $827 | $1,003 | $929 | $1,276 | **-$171***** |
| Total # of Rx | 21.3 | 29.8 | 22.8 | 32.2 | **-0.8** | 38.2 | 54.3 | 40.2 | 50.3 | **6.0**** | 34.0 | 47.4 | 35.6 | 46.2 | **2.8** |
| **Brand-name** | | | | | | | | | | | | | | | |
| OOP spending | $472 | $263 | $342 | $234 | **-$100***** | $1,139 | $873 | $849 | $704 | **-$156** | $957 | $647 | $681 | $551 | **-$179***** |
| OOP as a share of overall Rx $ (Brand+ Generic) | 0.17 | 0.10 | 0.15 | 0.11 | **-0.027***** | 0.22 | 0.15 | 0.16 | 0.13 | **-0.037**** | 0.22 | 0.16 | 0.16 | 0.13 | **-0.031**** |
| Total # of Rx | 9.6 | 5.3 | 8.4 | 5.2 | **-1.1**** | 20.0 | 14.3 | 18.7 | 14.2 | **-1.3** | 17.8 | 11.5 | 16.2 | 11.9 | **-2.0**** |
| Drug use as a share of overall utilization | 0.30 | 0.17 | 0.36 | 0.23 | **0.0004** | 0.45 | 0.32 | 0.52 | 0.42 | **-0.041**** | 0.44 | 0.30 | 0.44 | 0.42 | **-0.050**** |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Generic** | | | | | | | | | | | | | | | |
| OOP spending | $231 | $224 | $168 | $182 | **-$20** | $363 | $367 | $282 | $307 | **-$22** | $323 | $348 | $252 | $268 | **$8** |
| Total # of Rx | 22.6 | 24.5 | 14.5 | 16.1 | **0.3** | 30.3 | 39.6 | 21.6 | 23.7 | **7.2*** ** | 28.5 | 35.6 | 19.7 | 21.7 | **5.1** ** |

*Sources:* Author's analysis of data from the Medical Expenditure Panel Surveys, Household Component, 2008–13.

*Notes:* Estimates for the Part D and comparison groups are the marginal effect for each group before and after the ACA. Part D group is adults aged 65 years and older who had Medicare drug benefit but had no Medicaid coverage or private prescription drug coverage. The comparison group is Medicare beneficiaries aged 65 years and older and adults aged 55–64 years who had no Medicare drug benefit and Medicaid coverage but had private prescription drug coverage. OOP = out-of-pocket. Rx = prescription drugs. $ = expenditures. % = percent.

**Difference is statistically significant at 0.05 level. ***Difference is statistically significant at 0.01 level.

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